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Federal Register

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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: January 24, 2001, from 9:00 a.m. to Noon (E.S.T.)

WHERE: Office of the Federal Register
Conference Room
800 North Capitol Street, NW.
Washington, DC
(3 blocks north of Union Station Metro)

RESERVATIONS: 202–523–4538

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Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

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Presidential Documents

Title 3—

The President

Presidential Determination No. 2001–07 of December 19, 2000

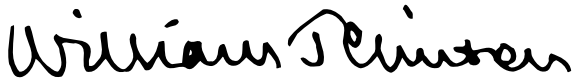
Presidential Certification To Waive Application of Restrictions on Assistance to the Government of Serbia and the Government of Montenegro

Memorandum for the Secretary of Defense [and] the Secretary of the Treasury

Pursuant to the authority vested in me by the laws of the United States, including section 1511 of the National Defense Authorization Act for Fiscal Year 1994 (Public Law 103–160), I hereby certify to the Congress that I have determined that the waiver of the application of subsections 1511(b) and (c) of Public Law 103–160 is necessary to achieve a negotiated settlement of the conflict in Bosnia-Herzegovina that is acceptable to the parties, to the extent that such provisions apply to the furnishing of assistance to the Government of Serbia and to the support of assistance from international financial institutions to the Government of Serbia and the Government of Montenegro.

Therefore, I hereby waive the application of these provisions with respect to such assistance and support.

The Secretary of Defense is authorized and directed to transmit a copy of this determination to the Congress and arrange for its publication in the **Federal Register.**



THE WHITE HOUSE,
Washington, December 19, 2000.

Billing code 5001–10–M

Memorandum of Justification for Presidential Certification Regarding the Waiver of Subsections 1511(b) and (c) of Public Law 103–160

Section 1511 of the National Defense Authorization Act for Fiscal Year 1994 (Public Law 103–160) (hereinafter ''section 1511'') was enacted into law in 1993 in the midst of the crisis in Bosnia and Herzegovina as the international community sought to put an end to years of conflict. Section 1511 provides in relevant part that ''[n]o funds appropriated or otherwise made available by law may be obligated or expended on behalf of the Government of Serbia'' and that ''[t]he Secretary of the Treasury shall instruct the United States executive director of each international financial institution to use the voice and vote of the United States to oppose any assistance from that institution to the Government of Serbia or the Government of Montenegro, except for basic human needs.'' These restrictions may be waived or modified, however, upon certification by the President that the waiver or modification ''is necessary . . . to meet emergency humanitarian needs, or . . . to achieve a negotiated settlement of the conflict in Bosnia-Herzegovina that is acceptable to the parties.'' This authority was exercised in February 1999 by the President to waive bilateral assistance restrictions with respect to the Government of Montenegro.

In light of the recent dramatic democratic transformation that has taken place in Serbia, we believe that it is important to exempt the Government of Serbia from the bilateral and multilateral assistance restrictions contained in section 1511 and the government of Montenegro from the provision's multilateral restrictions. Bilateral assistance from the United States and support for assistance in the International Financial Institutions (IFIs) are both critical to the consolidation of the fledgling Kostunica government. The United States must put itself in a position to voice its support of loans to the Governments of Serbia and Montenegro in the context of the FRY becoming a member in the IFIs. The first such provision of assistance—a loan of roughly $150 million under the IMF's post-conflict assistance policy to help the FRY clear its arrears at the IMF—will be voted upon as soon as December 20 together with a vote on FRY membership in that organization.

The election of Mr. Kostunica to the FRY Presidency could herald a new period of peaceful democratic development in the region. President Kostunica has made clear that he will work toward the full implementation of the Dayton Accords and work constructively on a variety of other issues related to the stability of the region. United States bilateral assistance as well as support for IFI assistance will help ensure the consolidation of power made by the Kostunica government. Such assistance will help prevent pro-Milosevic forces from regaining power in the FRY and resuming their obstructionist tactics and allow President Kostunica to continue to work towards peace and stability in the region. Therefore, waiver of application of the restrictions contained in subsections 1511(b) and (c) of Public Law 103–160, with respect to the Governments of Serbia and Montenegro, is warranted.

[FR Doc. 01–311
Filed 1–4–01; 8:45 am]
Billing code 5001–10–M

Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 302

[Docket No. 00–085–1]

District of Columbia; Movement of Plants and Plant Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are establishing regulations concerning the application for and issuance of certificates for the interstate movement of plants and plant products from the District of Columbia. The certificates will address the plant health status of plants and plant products moving interstate from the District of Columbia. This action will facilitate the interstate movement of plants and plant products from the District of Columbia.

DATES: This interim rule is effective January 5, 2001. We invite you to comment on this docket. We will consider all comments that we receive by March 6, 2001.

ADDRESSES: Please send your comment and three copies to: Docket No. 00–085–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 00–085–1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan Jones, Operations Officer, Invasive Species and Pest Management, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737; (301) 734–8247.

SUPPLEMENTARY INFORMATION:

Background

Until 1992, 7 CFR part 302 contained regulations governing the movement of plants and plant parts into and from the District of Columbia (referred to below as the District). The former regulations in part 302 contained a requirement that no nursery stock or herbaceous perennial plants, bulbs, or roots could be moved interstate from the District unless a certificate or permit was issued by the Animal and Plant Health Inspection Service (APHIS) stating that the plant or plant product was free from dangerous plant pests. This requirement was necessary because most States, and some Federal regulations, required that certain plants and plant products moving interstate be accompanied by a plant health certificate issued by the plant protection service of the originating State. Since the District has no official plant protection service, APHIS provides the District with plant health services, including inspecting and documenting the plant health status of plants and plant products being moved from the District.

In removing part 302, APHIS stated that it would continue to provide inspection and documentation services for plants and plant products moving from the District when inspection or documentation is required by Federal laws or regulations, or, when applicable, by the laws or regulations of countries that receive plants or plant products from the District.

This rule clarifies that, when inspection and documentation are requested for plants or plant products to be moved interstate from the District, the U.S. Department of Agriculture will provide those services. This rule will tell how to apply for inspection and obtain documentation for the interstate movement of plants and plant products from the District. A District of Columbia Plant Health Certificate is the form used to certify the plant pest status of plants or plant parts moving interstate from the District.

District of Columbia Plant Health Certificates are valid only for certifying plants *moving interstate* within the United States. Persons in the District of Columbia who require certification of plants *intended for export* to a foreign country need to obtain a Federal phytosanitary certificate under 7 CFR part 353. Persons interested in obtaining certification should contact the Plant Protection and Quarantine office at the Port of Baltimore, 2200 Broening Highway, Suite 140, Baltimore, MD 21224–6623; phone: (410) 631–0075; fax: (410) 631–0083; or visit the APHIS web site at *http://www.aphis.usda.gov/ppq/exports.*

This rule also includes definitions for ''inspector,'' ''interstate,'' and ''State''. We define an ''inspector'' as any employee of the Animal and Plant Health Inspection Service or other person authorized by the Administrator to inspect and certify the plant health status of plants and products under 7 CFR part 302. The term ''interstate'' means from any State into or through any other State. The term ''State'' means the District of Columbia, Puerto Rico, the Northern Mariana Islands, or any State, territory, or possession of the United States.

Immediate Action

Immediate action is necessary to facilitate the interstate movement of plants and plant products from the District of Columbia during the fall shipping season. Under these circumstances, the Administrator has determined that prior notice and opportunity for comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 to make this action effective less than 30 days after publication.

We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This interim rule provides that, the Animal and Plant Health Inspection Service will provide inspection and documentation services for plants or plant products moving interstate from the District of Columbia when inspection or documentation is required by Federal or State laws or regulations.

This rule simply puts into the regulations a process for inspecting and documenting plants and plant products that has been in effect for many years. Inspection and documentation are provided at no cost to applicants, and few, if any, entities, aside from the National Arboretum, regularly move plants and plant products interstate from the District of Columbia.

This rule will benefit the National Arboretum and others in the District who move plants and plant products interstate.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this interim rule have been submitted for emergency approval to the Office of Management and Budget (OMB). OMB has assigned control number 0579–0166 to the information collection and recordkeeping requirements.

We plan to request continuation of that approval for 3 years. Please send written comments on the 3-year approval request to the following addresses: (1) Docket No. 00–085–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. Please state that your comments refer to Docket No. 00–085–1 and send your comments within 60 days of publication of this rule.

This interim rule provides that when inspection or documentation is required by Federal or State laws or regulations, any plants and plant products moving interstate from the District of Columbia may be inspected for plant pests and their plant health status certified by a U.S. Department of Agriculture inspector prior to the interstate movement.

We are soliciting comments from the public concerning information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.2 hours per response.

Respondents: Plant producers and shippers.

Estimated annual number of respondents: 4.

Estimated annual number of responses per respondent: 50.

Estimated annual number of responses: 200.

Estimated total annual burden on respondents: 40 hours.

Copies of this information collection can be obtained from: Ms. Laura Cahall, APHIS' Information Collection Coordinator, at (301) 734–5360.

List of Subjects in 7 CFR Part 302

Agricultural commodities, Plant diseases, Plant pests, Plants (Agriculture), Quarantine, Transportation.

Accordingly, we are amending title 7, chapter III, by adding a new part 302 to read as follows:

PART 302—DISTRICT OF COLUMBIA; MOVEMENT OF PLANTS AND PLANT PRODUCTS

Sec.

Authority: Title IV, Pub. L. 106–224, 114 Stat. 438, 7 U.S.C. 7701–7772; 7 CFR 2.22, 2.80, and 371.3.

§ 302.1 Definitions.

Inspector. Any employee of the Animal and Plant Health Inspection Service or other person authorized by the Administrator to inspect and certify the plant health status of plants and products under this part.

Interstate. From any State into or through any other State.

State. The District of Columbia, Puerto Rico, the Northern Mariana Islands, or any State, territory, or possession of the United States.

§ 302.2 Movement of plants and plant products.

Inspection or documentation of the plant health status of plants or plant products to be moved interstate from the District of Columbia may be obtained by contacting Plant Protection and Quarantine, APHIS, Port of Baltimore, 2200 Broening Highway, Suite 140, Baltimore, MD 21224–6623; phone: (410) 631–0075; fax: (410) 631–0083.

(Approved by the Office of Management and Budget under control number 0579–0166)

Done in Washington, DC, this 27th day of December 2000.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01–241 Filed 1–4–01; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 212

[INS No. 2020–99]

RIN 1115–AF81

Update of the List of Countries Whose Citizens or Nationals Are Ineligible for Transit Without Visa (TWOV) Privileges to the United States Under the TWOV Program

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Interim rule with request for comments.

SUMMARY: The Transit Without Visa (TWOV) Program allows certain aliens to transit the United States en route to a specified foreign country without a passport or visa provided they are traveling on a carrier signatory to an agreement with the Immigration and Naturalization Service (Service) in accordance with section 233(c) of the Act. This interim rule updates the list of those countries that the Service, acting on behalf of the Attorney General and jointly with the Department of State, has determined to be ineligible for participation in the TWOV program. This rule also removes certain countries from the ineligible listing so that aliens from these countries can have their passport and visa requirements waived. This rule is intended to benefit the travelling public by expanding the number of countries whose citizens or nationals may transit the United States without a visa while preventing an increase in the abuse of the TWOV program by citizens or nationals of countries placed on the ineligible list.

DATES: *Effective Date*: This interim rule is effective February 5, 2001.

Comment Date: Written comments must be submitted on or before March 6, 2001.

ADDRESSES: Please submit written comments, in triplicate, to the Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, 425 I Street, NW, room 4034, Washington, DC 20536. Please include INS number 2020–99 on your correspondence to ensure proper and timely handling. Comments are available for public inspection at the above address by calling (202) 514–3048 to arrange for an appointment.

FOR FURTHER INFORMATION CONTACT: Robert F. Hutnick, Assistant Chief Inspector, Immigration and Naturalization Service, 425 I Street, NW, room 4064, Washington, DC 20536, telephone number (202) 616–7499.

SUPPLEMENTARY INFORMATION:

What Is the Authority for Participation in the TWOV Program?

Section 212(d)(4)(C) of the Immigration and Nationality Act (Act) provides authority for the Attorney General acting jointly with the Secretary of State (see Department of State regulation published elsewhere in this issue of the **Federal Register**) to waive nonimmigrant visa requirements for aliens who are proceeding in immediate and continuous transit through the United States and are using a carrier which has entered into a contract with the Service authorized under section 233(c) of the Act, in this case an Immediate and Continuous Transit Agreement on Form I–426, also known as a TWOV Agreement.

How Does This Interim Rule Amend the Regulations?

As the Service will no longer consider where a citizen of a particular country resides in determining under what conditions he or she may participate in the TWOV program, this interim rule amends the regulations by removing § 212.1(f)(2). This rule amends § 212.1(f)(3) by adding certain countries to the list of countries whose citizens are ineligible for TWOV privileges and re-designates § 212.1(f)(3) as § 212.1(f)(2).

How Will This Amendment Affect Carrier Liability in Pending Cases Involving the Bringing to the United States of an Alien Who Was Ineligible for TWOV Privileges?

This change will not have any effect on pending cases. The change enters into force on February 5, 2001, and applies to cases involving aliens who arrive in the United States on or after that date. If, before that date, a carrier violated the Act by bringing an alien who did not have a visa and was not eligible for TWOV privileges, the carrier's violation was complete at that time. The fact that an alien from that country may now be eligible for TWOV privileges, therefore, will not relieve the carrier of liability.

What Countries Will Benefit From This Action?

In the aftermath of the breakup of the former Soviet Union, the Service and the Department of State are waiving the passport and visa requirements for citizens of certain former Union of Soviet Socialist Republics which request to transit the United States without a nonimmigrant visa. These countries, from the former Soviet Union, include: Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan. They now will be afforded TWOV privileges.

Due to the democratization of the former Warsaw Pact countries, the citizens from these countries will be allowed to transit the United States without a nonimmigrant visa. The countries that will be afforded this privilege will include: Albania, Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, and Slovakia.

Due to the relative stability of certain countries that were formerly part of the Socialist Federal Republic of Yugoslavia, this rule will allow citizens of the following countries to use the TWOV program: Croatia, the Former Yugoslav Republic of Macedonia, and Slovenia.

Lastly, the improved stability in Mongolia and Vietnam will permit citizens of these countries to apply for TWOV privileges under this rule.

What Countries Are Being Added to the Ineligibility List in § 212.1(f)(2), as Revised?

The following countries are being added to § 212.1(f)(2) making the waiver of passport and visa requirement not available to an alien who is a citizen of that country (ineligible for TWOV privileges): Angola, Belarus, Burma, Burundi, Central African Republic, People's Republic of China, Congo (Brazzaville), Nigeria, Russia, Sierra Leone, Somalia, and Sudan.

Why Are Citizens From These Countries Now Ineligible for TWOV Privileges?

In determining which countries may or may not transit without visa, the Service (in conjunction with the Department of State) takes into consideration such things as, but not limited to, past abuse of the transit without visa privilege; the country's nonimmigrant visa refusal rate; whether the country grants United States nationals reciprocal treatment; the country's crime rate, the stability of the country; any security concerns; whether the country has diplomatic relations with the United States; and other relevant factors.

Good Cause Exception

The implementation of this rule as an interim rule, with a 60-day provision for post-promulgation public comments, is based on the ''good cause'' exceptions found at 5 U.S.C. 553(b)(B) and 553(d)(3). A notice and comment period

prior to implementation would have been unnecessary and contrary to the public interest. A portion of this rule expands the categories of persons who may transit the United States without a visa and is thus considered beneficial to both the traveling public and the United States Government. Moreover, this aspect of the rule grants or recognizes an exemption or relieves a restriction within the scope of the exception set forth at 5 U.S.C. 553(d)(1). Certain other countries have been added to the countries ineligible to transit without a visa. The reason for the necessity for implementation of this aspect of the interim rule is as follows: It is necessary to prevent an anticipated sharp increase in the abuse of the TWOV program by citizens of the countries placed on the list of ineligible TWOV countries. These countries are placed on the ineligible to TWOV list for a variety of reasons including past abuse of the transit without visa privilege; the country's nonimmigrant visa refusal rate; whether the country grants United States citizens reciprocal treatment; the country's crime rate; the stability of the country; any security concerns; and, whether the country has diplomatic relations with the United States, among other reasons.

Regulatory Flexibility Act

The Commissioner of the Immigration and Naturalization Service, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule governs whether a citizen of a particular country may transit the United States under the TWOV program. These aliens are not considered small entities as that term is defined under 5 U.S.C. 601(6).

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million or more in any 1-year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

This rule is not considered by the Department of Justice, Immigration and Naturalization Service, to be a ''significant regulatory actions'' under Executive Order 12866, section 3(f), Regulatory Planning and Review. Accordingly, the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

Executive Order 13132

This rule will not have substantial direct effects on the States, on the relationship between the Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988 Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

List of Subjects in 8 CFR Part 212

Administrative practice and procedure, Aliens, Passports and Visas.

Accordingly, part 212 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

1. The authority citation for part 212 continues to read as follows:

Authority: 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1187, 1225, 1226, 1227, 1228, 1252; 8 CFR part 2.

2. Section 212.1 is amended by:

a. Removing paragraph (f)(2);

b. Redesignating paragraphs (f)(3) and (f)(4) as paragraphs (f)(2) and (f)(3) respectively; and by

c. Revising newly redesignated paragraph (f)(2), to read as follows:

§ 212.1 Documentary requirements for nonimmigrants.

* * * * *

(f) * * *

(2) *Unavailability to transit.* This waiver of passport and visa requirement is not available to an alien who is a citizen of Afghanistan, Angola, Bangladesh, Belarus, Bosnia-Herzegovina, Burma, Burundi, Central African Republic, People's Republic of China, Congo (Brazzaville), Cuba, India, Iran, Iraq, Libya, Nigeria, North Korea, Pakistan, Russia, Serbia, Seirra Leone, Somalia, Sri Lanka, and Sudan.

* * * * *

Dated: December 21, 2000.

Mary Ann Wyrsch,

Acting Commissioner, Immigration and Naturalization Service.

[FR Doc. 01–354 Filed 1–4–01; 8:45 am]

BILLING CODE 4410–10–M

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 303, 337, and 362

RIN 3064–AC38

Activities and Investments of Insured State Banks

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Final rule and confirmation of interim final rule with changes.

SUMMARY: The FDIC is adopting a final rule to implement certain provisions of the Gramm-Leach-Bliley Act (G–L–B Act), governing activities and investments of insured state banks. Under the final rule, the FDIC adopts a streamlined certification process for insured state nonmember banks to follow before they may conduct activities as principal through a financial subsidiary. State nonmember banks will self-certify that they meet the requirements to carry out these activities, which will allow the banks to conduct the new activities immediately. There will be no delay for administrative approval or review, although the FDIC will evaluate these activities as part of its normal supervision process for safety and soundness standards pursuant to the FDIC's authority under section 8 of the Federal Deposit Insurance Act (FDI Act). The final rule confirms, with modifications, an interim rule that has been in effect since March 11, 2000. To eliminate unnecessary provisions and make technical amendments, the FDIC also has revised its rule implementing sections 24 and 18(m) of the FDI Act dealing with other activities and investments of insured state banks.

EFFECTIVE DATE: January 5, 2001.

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SUPPLEMENTARY INFORMATION:

I. Background

On March 23, 2000, the FDIC published an interim final rule with request for comment (65 FR 15526) to implement certain provisions of the G–L–B Act (Pub. L. 106–102), which President Clinton signed into law on November 12, 1999. Section 121(d) of the G–L–B Act amended the FDI Act (12 U.S.C. 1811 *et seq.*) by adding a new section 46 (12 U.S.C. 1831w). New section 46(a) of the FDI Act provides that an insured state bank may control or hold an interest in a subsidiary that engages as principal in activities that would be permissible for a national bank to conduct only through a ''financial subsidiary,'' subject to certain conditions. Because section 46(a) applies only to ''as principal'' activities, state nonmember banks may engage in agency activities without considering the requirements of this rule or section.

As set forth in the interim final rule, section 121(a) of the G–L–B Act permits national banks to control or hold an interest in a financial subsidiary, which is a new type of subsidiary governed by new section 5136A of the Revised Statutes. A financial subsidiary may engage in specified newly authorized activities that are financial in nature and activities that are incidental to financial activities, if the bank and the subsidiary meet certain requirements and comply with stated safeguards. A financial subsidiary also may combine these financial subsidiary activities with activities that are permissible for national banks to engage in directly. The financial subsidiary activities include many of the activities which are authorized for the new ''financial holding companies'' as laid out in new section 4(k) of the Bank Holding Company Act (BHCA) (12 U.S.C. 1841 *et seq.*) as created by section 103(a) of the G–L–B Act. In the future, the Secretary of the Treasury (Treasury) and the Board of Governors of the Federal Reserve System (FRB) may determine that additional activities are financial in nature and therefore authorized for a financial subsidiary of a national bank.

Section 121(d) of the G–L–B Act, which creates new section 46 of the FDI Act, permits state banks to control or hold an interest in a financial subsidiary that engages in activities as principal. To qualify, a state bank must comply with four statutory conditions and a mandatory Community Reinvestment Act (CRA) (12 U.S.C. 2901 *et seq.*) requirement found in section 103(a) of the G–L–B Act, which added a new subsection (4)(l)(2) to the BHCA (12 U.S.C. 1843(l)(2)).

The FDIC has a long history of reviewing applications from state banks to engage in activities not permissible for national banks under section 24 of the FDI Act (12 U.S.C. 1831a) as implemented through part 362 of the FDIC's rules and regulations. As stated in the preamble to the interim final rule, certain activities which the FDIC previously addressed under section 24 and subpart A of part 362, such as general securities underwriting, are now authorized for a financial subsidiary of a national bank. As a result, the FDIC will now analyze the commencement of such activities under section 46(a) rather than section 24, and the FDIC will apply the restrictions contained in subpart E rather than those in subpart A of part 362. These statutory changes necessitate that the FDIC conform its regulation by limiting the sections pertaining to such activities from subpart A to existing subsidiaries.

Other activities conducted as principal, such as real estate development or investment, which are prohibited to national bank financial subsidiaries, are outside the scope of section 46(a). These activities will continue to be governed by section 24 and subpart A of part 362. State banks that wish to engage in activities prohibited to national banks may continue to seek the FDIC's consent by filing a notice or application. Should the Treasury and FRB in the future determine that additional activities are authorized for a financial subsidiary of a national bank, state nonmember banks commencing such activities for the first time after such determinations will have to proceed under section 46(a). However, banks that obtained FDIC consent under section 24, whether by notice, order, or regulation before such determination may continue to engage in any such activity pursuant to the requirements imposed under section 24.

II. Comments Received

The FDIC received 15 comments in response to the interim final rule. The comments came from four trade associations, four state banking departments, two community-based associations, a law firm, a state regulators association, a bank holding company, and four United States Senators. Three commenters expressed support for the FDIC's interim final rule. The other commenters expressed various objections to the rule. Several of the commenters recommended specific changes to the interim final rule. A discussion of these comments and the changes and additions made to the interim final rule and the rule implementing sections 24 and 18(m) of the FDI Act are discussed in the section by section analysis. The final rule adopts a more streamlined process than the interim rule. A summary of the comments follows.

The FDIC's interim rule to implement section 46 of the G–L–B Act provided that section 46 is the exclusive method for an insured state nonmember bank to engage in ''financial subsidiary activities.'' Six of the comments, including a comment from three United States Senators, argued that Congress intended to preserve the FDIC's authority to approve activities under section 24. These commenters argued that the preservation of authority provision [1] was meant to ensure that the FDIC's authority to approve activities under section 24 is not diminished by section 46, and that section 46 was intended to permit (but not require) state banks to use the financial subsidiary vehicle to conduct financial or incidental activities. On the other hand, another United States Senator argued that the interim final rule was consistent with the statutory language and legislative history of the G–L–B Act and that the interim final rule correctly applies the G–L–B Act to require state banks to use the financial subsidiary vehicle to conduct financial or incidental activities.

Four commenters argued that if section 46 was read as the only method under which a state nonmember bank could engage in financial subsidiary activities, then innovation in the state bank system would be stifled and the dual banking system would be undermined. Some commenters argued that Congress' purpose behind section 46 was to assure state banks that they would not be disadvantaged if national banks are authorized to engage in activities through financial subsidiaries that the FDIC concludes would not be permitted to state banks under section 24. The four commenters also noted that although certain activities which were previously addressed by the FDIC under section 24 are now authorized for a national bank financial subsidiary, the grandfather provisions of the G–L–B Act [2] make it clear that any activities lawfully conducted prior to the G–L–B Act through a subsidiary under section

[1] 12 U.S.C. 1831w(d)(1).

[2] 12 U.S.C. 1831w(b).

24 survive. These commenters believed that Congress intended to preserve the FDIC's section 24 authority regardless of whether the activities are permissible for national bank financial subsidiaries and that the requirements placed on state banks under section 24 have proven to be appropriate.

With regard to the structure of the FDIC's interim rule, half of the commenters believed the FDIC's rule was more restrictive than the Office of the Comptroller of the Currency's (OCC's) and the FRB's comparable rules. They argued that the inconsistencies between the FDIC's rule and the other federal banking agencies' rules have the effect of competitively disadvantaging state nonmember banks. Some of them believed that the potential disadvantage to state nonmember banks could lead to confusion and increased regulatory burden, all for no apparent safety and soundness reason.

One commenter noted that while section 24 of the FDI Act expressly requires state banks to apply to the FDIC before they can engage in any activity not authorized for national banks, section 46 does not have a similar requirement. This commenter contended that the FDIC recognized that section 46 does not include a discretionary ''gatekeeping'' regulatory authority since the FDIC stated in its preamble to the interim final rule that it was imposing requirements in addition to those specified in the G–L–B Act. Other commenters read section 46 as not requiring state banks to seek FDIC approval prior to engaging in covered activities. One commenter argued that section 8 of the FDI Act and section 114(c) of the G–L–B Act, which provides that the FDIC may impose restrictions or requirements on relationships or transactions between a state nonmember bank and a subsidiary of a state nonmember bank, do not provide the FDIC with authority to require state nonmember banks to obtain prior approval before a subsidiary engages in financial subsidiary activity.

Another commenter contended that the prior approval requirement is not necessary because the activities will have been approved by the Congress or the Treasury and the FRB. This commenter believed that an approval process is only appropriate where the activity is not already authorized for a national bank and noted that the FDIC has sufficient authority under general supervisory authority to intervene should it be necessary.

Also with regard to the structure of the FDIC's rule, several of the commenters favored a more uniform approach to the rules. These commenters believed that all of the federal banking agencies' rules on financial subsidiary activities should be consistent, and that because the rules of the OCC and the FRB are similar, the FDIC should adopt a rule that is as consistent with those rules as is possible given the differing statutes. Specifically, some of the commenters state that the OCC's self-certification, streamlined approval process should be adopted by the FDIC because it would reduce regulatory burden and establish parity for state banks and national banks. Other commenters believed the FDIC's rule should be consistent with the FRB's rule that requires only a 15-day approval as opposed to the FDIC's 30-day approval.

The FDIC also received comment on the scope of the activities covered by the rule. Some of the commenters contended that the FRB's rule provides more flexibility to the state system because it excludes from coverage activities that the state member bank is permitted to engage in directly, but chooses to do so in a subsidiary, or conducts in a subsidiary as is otherwise authorized by federal law. These commenters believed the FDIC should permit state nonmember banks to follow section 24 if the state nonmember bank is authorized to engage in the activity directly or in any state bank subsidiary that is otherwise expressly permitted under state or federal law. They believe this would allow state nonmember banks to continue to choose where to conduct these activities and not force state banking authorities to conform determinations to that of the OCC.

Some commenters expressed concern that the FDIC's rule would require a state nonmember bank that is conducting an activity approved under section 24 after the effective date of the G–L–B Act that is later determined to be permissible for a national bank financial subsidiary to switch from section 24 to section 46. These commenters are concerned about the burden and uncertainty entailed in altering the subsidiary's structure and operations so as to bring it into compliance with the statutory conditions of section 46(a), rather than the conditions the FDIC previously imposed under section 24. Several commenters believed this will create potentially significant administrative, compliance, personnel, and legal burdens, and will cast a pall of uncertainty over the FDIC's section 24 post G–L–B Act approvals because it will be unclear whether the conditions placed upon the activity will change at some unknown date in the future. They contend that this uncertainty also would be disruptive to bank supervisors who would have to examine banks under a different set of conditions. One of the commenters found this to be inconsistent with FDIC practice and detrimental to its authority under section 24 and believed that once an activity is approved under section 24, it should not have to be re-qualified under section 46.

The FDIC received a small number of comments on other areas of concern. Two commenters contended that the FDIC's rule would limit existing state authority. Three commenters raised concern about the CRA rating requirement. Two of them asked that the FDIC's rule allow for public comment with regard to the CRA rating requirement because they felt the public should be given the opportunity to comment on a bank's plans to engage in financial subsidiary activity. These commenters also asked that in cases where the CRA rating is a low satisfactory, the FDIC should condition approval of new activities on specific improvements in a bank's CRA performance rating. One of the commenters believed the FDIC was importing a CRA standard that Congress did not impose on section 24 directly or through the G–L–B Act by forcing state banks to conduct activities in financial subsidiaries under section 46 requirements instead of section 24 requirements. This commenter suggested that because most state banks have a satisfactory or better rating, the FDIC rule disadvantages a majority of them for the purpose of preventing a few banks from evading the CRA requirements.

Another commenter believed that the FDIC's rule should require that state nonmember banks be well-managed just like national banks and state member banks because this will promote consistency and alleviate FDIC concerns that may be behind the FDIC's reason for advance review of section 46 activities.

Last, the FDIC received some comments seeking clarification of certain provisions in the interim final rule. One commenter asked that the FDIC's rule clearly provide that authorizations given to state nonmember banks prior to the FDIC's adoption of the current subpart A of part 362 are covered by the grandfather provision. Another commenter asked for further clarification on the financial and operational safeguards requirement.

We have responded to these comments by conforming the FDIC's definition of ''financial subsidiary'' to the definition adopted by the FRB and adopting a streamlined self-certification

process similar to the OCC but without any waiting period. More specific discussions of the FDIC's particular responses to the comments are found in the section by section analysis.

III. Final Rule—Section by Section Analysis

Part 362

A. Subpart A—Activities of Insured State Banks

The FDIC made several technical amendments to subpart A. As noted in the preamble to the interim final rule, the G–L–B Act provisions amending the FDI Act created a need for the elimination and clarification of certain provisions of subparts A and B. We discuss the specific changes below.

Section 362.1 Purpose and Scope

The references to safety and soundness concerns relating to real estate investment activities of insured state nonmember banks and their subsidiaries in subpart B of part 362 have been eliminated from paragraph (c) of § 362.1. The G–L–B Act expressly provides that national banks may not engage in real estate development and real estate investment activities [3] through a financial subsidiary or operating subsidiary. Thus, the safety and soundness standards set forth in subpart B of part 362 relating to real estate investment activities of a type that are not permissible for a national bank, but may be otherwise permissible for a subsidiary of a national bank, are not necessary. Any insured state nonmember bank desiring to engage in real estate investment activities through a subsidiary will continue to be subject to the requirements relating to such activities in subpart A.

Section 362.2 Definitions

We are changing the definition of ''subsidiary'' in paragraph (r) of § 362.2 to make it consistent with the exception in § 362.4(b)(3)(ii), which permits a subsidiary of an insured state bank to own equity securities of certain companies if, among other things, the subsidiary controls the company or the company is controlled by insured depository institutions. Thus, a more appropriate definition for ''subsidiary'' would include any company that is owned or controlled directly or indirectly by one or more insured depository institutions. The rule has been changed accordingly.

Section 362.4 Subsidiaries of Insured State Banks

Paragraphs (b)(5) (i) and (ii) of § 362.4 formerly provided the requirements for a state nonmember bank to engage in real estate investment activities and general securities underwriting through a majority-owned subsidiary. Under the G–L–B Act, a financial subsidiary of a national bank is permitted to engage in general securities underwriting activities. Thus, state nonmember banks may commence conducting this activity pursuant to section 46(a) of the FDI Act through a financial subsidiary as set forth in subpart E. Applications to engage in general securities underwriting will no longer be processed under section 24 and subpart A of part 362. However, the regulatory language found in § 362.4(b)(5)(ii) will continue to govern those banks engaged in this activity as of the effective date of the G–L–B Act. The restrictions contained in this section will continue to apply only to existing state bank subsidiaries that are covered by section 46(b) of the FDI Act.[4]

In § 362.4(c)(2)(vi), the word ''officers'' is more inclusive than the FDIC had intended and has required the FDIC to provide repeated informal interpretations that ''officers'' should be read as ''executive officers.'' To eliminate the need for repeated informal interpretations and to utilize the definition for ''executive officers'' already contained in part 362, this paragraph of the rule has been changed to conform to the defined term.

Section 362.5 Approvals Previously Granted

Due to the passage of time, some of the transitional deadlines contained in this section have expired and the provisions are no longer of any effect. We removed and reserved § 362.5(b) (1), (2), and (3), which relate to securities underwriting activities, grandfathered insurance underwriting activities, and the ownership of the stock of certain corporations approved by the FDIC prior to January 1, 1999.

B. Subpart B—Safety and Soundness Rules Governing Insured State Nonmember Banks

Section 362.6 Purpose and Scope

Section 362.8 Restrictions on Activities of Insured State Nonmember Banks

We removed the safety and soundness standards governing real estate investment activities formerly found in this section of the rule because they are no longer necessary. As provided in the G–L–B Act, national bank financial subsidiaries are not permitted to engage in real estate development or real estate investment activities, unless otherwise expressly authorized by law.[5]

Regarding the separation standards that any affiliate company that engages in general securities underwriting and any state nonmember bank must meet, we also revised the introductory paragraph to more clearly cover the appropriate entities in the scope of the rule. Now, the language provides that unless the affiliated company that engages in general securities underwriting is a subsidiary of an entity that is supervised by a federal banking agency, the affiliated company that engages in general securities underwriting and the state nonmember bank must meet the separation standards. To conform to the less burdensome separation standards found in the sections implementing section 46, we also streamlined the separation standards to lessen the burden of compliance with this section.

On December 1, 1998 (63 FR 66339), the FDIC proposed and published an amendment to part 362 that added safety and soundness standards to govern insured state nonmember banks that engage in the public sale, distribution or underwriting of stocks, bonds, debentures, notes or other securities through a subsidiary if those activities are permissible for a national bank subsidiary but are not permissible for the national bank itself. In addition, the FDIC proposed and published a proposal (63 FR 66339) to require that insured state nonmember banks file a notice before commencing any activities permissible for subsidiaries of a national bank that are not permissible for the parent national bank itself. This proposal also contained language to remove and reserve the provisions found in § 337.4 entitled, ''Securities Activities of Subsidiaries of Insured State Banks: Bank Transactions with Affiliated Securities Companies.'' The effect of these amendments was described as requiring banks to notify the FDIC prior to conducting securities or other activities through subsidiaries that are not permissible for the bank itself. The FDIC also stated that when the FDIC adopts these amendments in final form, the FDIC's securities activities regulation would be fully consolidated in part 362. Only two comments were received on this proposal, both of which supported the elimination of § 337.4. One of the commenters stated that it agrees with

[3] 12 U.S.C. 24a(a)(2)(B)(ii).

[4] 12 U.S.C. 1831w(b).

[5] 12 U.S.C. 24a(a)(2)(B)(ii).

the FDIC's assertion that the revised standards contain more flexible physical separation requirements than those currently imposed on the bank and its subsidiaries in § 337.4. This most recent and still outstanding proposal was limited in scope and followed the more comprehensive revision of part 362 that was published in final form in the Federal Register on the same day and became effective on January 1, 1999.

During this interim period, § 337.4 has continued to be operative to govern separation standards for affiliations among banks and general securities underwriting companies when coverage is not provided under § 362.8(b). Thus, § 337.4 currently provides separation standards for any such affiliated entity that may not otherwise be covered by the language in the currently effective version of § 362.8(b). As we indicated in the December 1, 1998 Proposed Rule, we intended to reserve and remove § 337.4. As a part of that effort, we are moving the coverage of those entities into § 362.8 and making the standards more flexible and reducing the regulatory burden. By modifying the language of § 362.8(b) in the manner suggested, the coverage of separation standards also is made more transparent to banks and their general securities underwriting affiliates.

As set forth in this final rule, the separation standards under § 362.8, which will be imposed on these affiliates, are nearly identical to the separation standards to be imposed on financial subsidiaries of insured state nonmember banks engaged in underwriting securities under new § 362.18(a)(4)(B). Because of the G–L–B Act, financial subsidiaries of insured state nonmember banks engaged in general securities underwriting are subject to two additional requirements, which are a CRA rating requirement applicable to the bank and all insured depository institution affiliates and compliance with the financial and operational safeguards applicable to a financial subsidiary of a national bank. The FDIC believes it is appropriate to have substantially the same requirements apply to securities underwriting activities, whether they are conducted by an affiliate engaging in general securities underwriting under subpart B or a financial subsidiary engaging in general securities underwriting under new subpart E. The FDIC believes that it makes no difference to the safety and soundness of the insured state nonmember bank whether the general securities underwriting activity is conducted by a securities underwriting affiliate under subpart B or in a financial subsidiary under new subpart E. To achieve that consistency, the FDIC is adopting comparable standards for all of these entities in its final rule. In addition, to provide flexibility to the regulated entities, the FDIC will consider applications for relief from these separation safeguards in appropriate circumstances.

Section 362.7 Definitions

In paragraph (a) of § 362.7, ''affiliate'' is defined as any company that directly or indirectly, through one or more intermediaries, controls or is under common control with an insured state nonmember bank but does not include a subsidiary of an insured state nonmember bank. We have changed this definition to be consistent with the definition in subpart E of part 362, which provides that an ''affiliate'' has the same meaning contained in section 3 of the FDI Act (12 U.S.C. 1813). That section incorporates by reference the definition in section 2 of the BHCA (12 U.S.C. 1841(k)), which provides that an ''affiliate'' means any company that controls, is controlled by, or is under common control with another company. For the purpose of uniformity and to avoid confusion and inconsistency, we will now use a definition for ''affiliate'' that is the same in all subparts of part 362 that use the term ''affiliate.'' Therefore, the rule has been changed accordingly.

We also removed the definition for ''real estate investment activity'' in paragraph (b) of § 362.7 because of the changes to the substantive §§ 362.6 and 362.8.

C. Subpart C—Activities of Insured Savings Associations

Section 362.10 Definitions

Because of the substantive change to the definition for ''affiliate,'' and our decision to use a uniform definition for ''affiliate'' throughout part 362, we have removed the prior definition for ''affiliate'' in paragraph (a) of § 362.10 and replaced it with a simple cross-reference to the newly defined term in subpart B of part 362.

Section 362.12 Service Corporations of Insured State Savings Associations

In paragraph (b)(2)(i) of § 362.12, an incorrect reference to ''bank'' has been changed to ''savings association'' since that provision pertains to activities of service corporations of insured state savings associations.

We removed the safety and soundness standards and the requirements governing service corporations of insured state savings associations conducting securities underwriting activities under paragraphs (b)(2)(ii) and (b)(4) of § 362.12 because no insured state savings associations have asked the FDIC for permission to engage in this activity. The FDIC's decision to remove these provisions from the rule should not be construed as a prohibition to engage in securities underwriting activity by service corporations of insured state savings associations. Rather, the FDIC believes that any request to engage in such activity could be better handled by a custom drafted order that deals with the particular circumstances of the institution requesting the authority, rather than through a general rule that also will require interpretation. We removed the authority granting provisions for insured state banks to commence securities underwriting activities from subpart A because the authority to commence engaging in that activity is now found in section 46 of the FDI Act and subpart E. However, any subsidiaries lawfully in existence and engaging in these activities under this authority on November 11, 1999 will continue to be covered under the regulatory language found in subpart A. We also removed the comparable authority granting provisions from subpart C of part 362 governing savings associations. Hereafter, any service corporation of an insured state savings association desiring to engage in securities underwriting activities through a service corporation may submit an application to the FDIC for consent to engage in the activity. At such time, the FDIC will determine the appropriate safety and soundness standards that should be applicable to the institution's particular situation.

D. Subpart E—Financial Subsidiary Activities of Insured State Nonmember Banks

Section 362.16 Purpose and Scope

As provided in the interim final rule, the FDIC will continue to implement section 46(a) through subpart E of part 362. Section 362.16 sets out the purpose and scope of the subpart, including the scope of the activities covered. Subpart E applies to any financial subsidiaries of state nonmember banks.

Several commenters stated that Congress intended to preserve the FDIC's authority to approve activities under section 24 given the specific reference in section 46(d). Section 46(d) provides that section 46 shall not be construed as superseding the authority of the FDIC to review subsidiary activities under section 24. Some commented that if section 46(a) is read

as the only method under which a state nonmember bank could engage in financial subsidiary activities, then innovation in the state bank system would be stifled and the dual banking system would be undermined. In light of the comments received, the FDIC has reconsidered some of its interpretation of section 46 and other relevant provisions of the G–L–B Act. For example, the FDIC has adopted the definition for ''financial subsidiary'' used by the FRB to exclude activities that may be carried out directly by the bank. However, the other comments have not dissuaded the FDIC as to the correctness of much of its interpretation of section 46. The FDIC believes that the statutory language in section 46 that preserves the authority of the FDIC under section 24 and the grandfather provision for subsidiaries lawfully in existence before enactment of the G–L–B Act would not be necessary, if section 46 was intended to serve only as an alternative mechanism for approving financial activities. This interpretation also is consistent with the FDIC's historic practices in applying section 24 to activities: Once an activity becomes permissible for a national bank, section 24 no longer applies to insured state nonmember banks that want to commence engaging in the activity. The FDIC believes that this construction of the statute will have little effect on innovation in the state bank system because state nonmember banks are still free to seek the FDIC's approval under section 24 to engage in innovative activities that are not permissible to national banks directly or through a financial subsidiary. The only constraint that this interpretation imposes on state nonmember banks is that insured state nonmember banks will have to conform to standards that are consistent with those imposed on national banks and state member banks when engaging in the same activities as principal through a financial subsidiary. State banks under the authority of the States are free to innovate with respect to all other activities with the FDIC's consent under section 24, as Congress intended and expressed in section 46(d).

Some commenters expressed apprehension about the impact of the FDIC's interpretation upon a state nonmember bank subsidiary that obtains a section 24 approval to engage in an activity, if the Treasury and FRB subsequently authorize the same activity for financial subsidiaries of national banks. The statutory grandfather under section 46(b) covers subsidiary activities lawfully conducted as of the G–L–B Act's enactment date. These commenters infer from this grandfather provision that section 24 approvals issued by the FDIC after enactment of the G–L–B Act are subject to being voided if the activity in question later becomes subject to section 46(a).

The FDIC recognizes that this paradox exists under one possible interpretation of section 46(a). However, the FDIC wishes to clarify that, under the FDIC's interpretation of section 46, this is not the case. As the FDIC stated in the preamble to the interim final rule, activities will become subject to section 46(a) rather than section 24 only if the Treasury and FRB declare activities to be financial in nature and permissible for financial subsidiaries of national banks. However, this means only that state nonmember banks seeking to commence such activities for the first time *after* a Treasury and FRB determination will proceed under section 46(a). If a state nonmember bank has obtained a section 24 approval to conduct the activity before the Treasury and FRB determination, the state nonmember bank remains subject to any section 24 approval obtained from the FDIC, and the section 24 approval conditions remain in effect. Existing orders under section 24 and part 362 continue to apply to the particular banks bound by those orders until modified by the FDIC.

Because section 46 does not explicitly address what is to be done in this situation the FDIC is exercising its administrative expertise to determine the outcome. In resolving this issue, the FDIC must determine how to best interpret section 46. Congress, in reserving the FDIC's section 24 authority over activities not covered by section 46, clearly intended to foster state innovation with respect to these reserved activities. In order for state nonmember banks to be able to venture into these innovative opportunities still open to them as a result of Congress' action, a certain amount of predictability is necessary. A state nonmember bank contemplating whether to engage in a line of business subject to the FDIC's conditions under section 24 must be reasonably comfortable that the ground rules will not change suddenly at some uncertain future point. Therefore, the FDIC's interpretation best effectuates Congress' intent to foster innovation as a continuing dynamic within the dual banking system.

Section 362.17 Definitions

Section 362.17 of the final rule contains the definitions used in this subpart. Rather than repeating terms defined in subpart A, certain of the definitions contained in § 362.2 are incorporated into subpart E by reference. The definitions of ''activity'', ''company,'' ''control,'' ''insured depository institution,'' ''insured state bank,'' and ''subsidiary'' apply as they are described in subpart A. In a similar way, we have incorporated into subpart E by reference the definition of ''affiliate'' as it is described in subpart B. These definitions remain consistent throughout part 362 to avoid confusion among the various subparts of the rule.

This subpart E sets forth the requirements for financial subsidiaries of insured state nonmember banks. In response to the comments, the FDIC has changed the scope of the rule by defining ''financial subsidiary'' in the same way as the FRB did in its rule, except that the definition is conformed to the circumstances of the state nonmember bank. Thus, any activity that may lawfully be conducted by the state nonmember bank directly is not required to be conducted through a financial subsidiary whenever the bank employs a subsidiary to conduct the activity.

This result was reached because of comments the FDIC received that the interim rule was more restrictive than the FRB's rule governing financial subsidiaries. This view is based on the fact that the FRB's rule excludes from the definition of ''financial subsidiary'' those activities that the state member bank is permitted to engage in directly or through a subsidiary of a state member bank that is otherwise authorized by federal law. The commenters say the FDIC's interim rule competitively disadvantages insured state nonmember banks.

In response to the comments, the FDIC has adopted the FRB's definition while conforming it to the circumstances of the state nonmember bank. In the final rule, ''financial subsidiary'' is defined as any company that is controlled by one or more insured depository institutions other than a subsidiary that only engages in activities that the state nonmember bank is permitted to engage in directly and that are conducted on the same terms and conditions that govern the conduct of the activities by the state nonmember bank; or the state nonmember bank is specifically authorized to control by the express terms of a federal statute (other than section 46(a) of the FDI Act), and not by implication or interpretation, such as the Bank Service Company Act (12 U.S.C. 1861 *et seq.*).

In the interim final rule, the FDIC implicitly carried the literal statutory restriction from the definition of

financial subsidiary in section 5136A. In contrast, the FRB substituted the state member bank for the national bank when reproducing this definition in its regulation.

The FDIC has been persuaded by the comments and has revised its rule to make it consistent with the FRB's rule by defining a financial subsidiary to exclude subsidiaries that conduct only activities that may be conducted by the state nonmember bank directly. The goals of parity among the banking charters and making banking regulations as uniform as possible among the banking agencies are enhanced by this interpretation and are goals that the FDIC consistently pursues whenever possible.

In the interim rule, the FDIC defined ''affiliate'' differently in subpart E from subparts B and C. The subpart E definition incorporated the definition from section 3 of the FDI Act (12 U.S.C. 1813). To make the entire regulation more internally consistent, the definition of ''affiliate'' has been changed in subparts B and C to match the subpart E definition. Subpart E now incorporates the definition from subpart B, which incorporates the definition from section 3 of the FDI Act (12 U.S.C. 1813). Thus, the final rule has the same definition of ''affiliate'' in subpart E as is contained in the interim rule, but the source is different.

Section 362.17 also includes definitions for ''tangible capital,'' ''Tier 2 capital'' and ''well-managed.'' These were included because of the comments we received in favor of making the FDIC's rule consistent with the OCC's and FRB's rules. As discussed below with regard to § 362.18(a), the FDIC requires that any insured state nonmember bank desiring to control or hold an interest in a financial subsidiary or commence any new financial activity pursuant to section 46(a) must certify, among other things, that it is well-managed. This is not required by section 46(a), but as discussed below, the FDIC has decided to revise the interim rule to allow for a self-certification process similar to the OCC's, except that the FDIC's self-certification process does not impose any waiting period on a state nonmember bank before the state bank may engage in any activity pursuant to section 46(a). The state nonmember bank only has to file a notice with the FDIC and certify to certain facts. Compliance with the requirements will be evaluated using the FDIC's usual supervisory powers. This process is more streamlined than the 30-day processing that was included in the FDIC's interim rule. However, for safety and soundness reasons, the insured state nonmember bank must certify that it is well-managed in order to qualify for this streamlined process. Although the G–L–B Act imposes a well-managed requirement on national banks and state member banks as well as their insured depository institution affiliates, the FDIC's statute does not include such a requirement. In adopting the streamlined notice process with no waiting period, the FDIC believes it is necessary to impose the requirement that the state bank be well-managed by this regulation. The FDIC will, however, consider applications for relief from the ''well-managed'' requirement in appropriate circumstances.

Section 362.18 Financial Subsidiaries of Insured State Nonmember Banks

Section 362.18(a) requires that an insured state nonmember bank file a notice that contains the usual information required for a notice or application under § 303.121(b) prior to acquiring control of, or holding an interest in a financial subsidiary under section 46(a). In addition, the insured state nonmember bank must certify that it is well-managed; that it and all of its insured depository institution affiliates are well-capitalized; and that the insured state nonmember bank will comply with the capital deduction requirement, which is found in the statute and in the OCC's and FRB's rules. The insured state nonmember bank must deduct the aggregate amount of its outstanding equity investment, including retained earnings, in all financial subsidiaries that engage in activities as principal pursuant to section 46(a), from the bank's total assets and tangible equity and deduct such investment from its total risk-based capital (this deduction shall be made equally from Tier 1 and Tier 2 capital). An insured state nonmember bank may not commence any new activity under section 46(a) or directly or indirectly acquire control of a company engaged in any such activity pursuant to § 362.18, if the bank or any of its insured depository institution affiliates received a rating of less than satisfactory in its most recent CRA examination.[6] An insured state nonmember bank controlling or holding an interest in a financial subsidiary also must comply with sections 23A and 23B of the Federal Reserve Act (12 U.S.C. 371c and 371c–1), as amended by the G–L–B Act and meet the financial and operational safeguards required by section 5136A(d) of the Revised Statutes of the United States (12 U.S.C. 24a(d)), unless otherwise determined by the FDIC.

However, the FDIC continues to be concerned that adequate separation standards exist between an insured state nonmember bank and its financial subsidiary when the financial subsidiary engages in certain types of securities underwriting activities. Thus, if the financial subsidiary of the insured state nonmember bank will engage in the public sale, distribution or underwriting of stocks, bonds, debentures, notes, or other securities activity of a type permissible for a national bank only through a financial subsidiary, then the state nonmember bank and the financial subsidiary also must comply with the same separation standards as are applicable to affiliates of insured state nonmember banks that are not controlled by an entity regulated by a federal banking agency under subpart B. These separation standards require that the securities business of the financial subsidiary be physically separate and distinct in its operations from the operations of the bank; that the financial subsidiary conduct its securities business pursuant to independent policies and procedures designed to inform customers and prospective customers of the financial subsidiary that the financial subsidiary is a separate organization from the insured state nonmember bank and that the insured state nonmember bank is not responsible for and does not guarantee the obligations of the financial subsidiary. In addition, the bank must adopt policies and procedures, including appropriate limits on exposure, to govern its participation in financing transactions underwritten by its financial subsidiary and may not express an opinion on the value or the advisability of the purchase or sale of securities underwritten or dealt in by its financial subsidiary, unless the bank notifies the customer that the entity underwriting, making a market, distributing or dealing in the securities is a financial subsidiary of the bank.

Notwithstanding the comments on the CRA requirement, the FDIC will not revise its rule to allow for public comment with regard to the CRA rating requirement or give the FDIC the authority to condition approval of new activities on specific improvements in a bank's CRA performance rating because the FDIC does not have the authority to impose such additional CRA requirements on state nonmember banks.

The final rule provides that an insured state nonmember bank may not acquire control or hold an interest in a financial subsidiary that engages in

[6] This prohibition is required by section 4(l)(2) of the BHCA as enacted in section 103(a) of the G–L–B Act which is codified at 12 U.S.C. 1843(l)(2).

financial activities as principal or commence any such new activity pursuant to section 46(a) of the FDI Act, unless the insured state nonmember bank submits a notice under the procedures set forth in § 362.18(a). An insured state nonmember bank that submits such a notice must comply with the requirements of § 362.18(a),(b), (c) and (d), as applicable. The bank must file the notice with the appropriate regional office prior to acquiring control of, or holding an interest in, a financial subsidiary that engages in financial activities as principal that a national bank must conduct through a financial subsidiary. Similarly, the bank must file such notice prior to commencing any additional as principal financial activity under section 46(a). Before acquiring control of a financial subsidiary or commencing any new as principal financial activity under section 46(a), the insured state nonmember bank also must meet the CRA requirement and certify that it is well-managed; that it and all of its insured depository institution affiliates are well-capitalized; and that the insured state nonmember bank will comply with the capital deduction requirement.

The insured state nonmember bank is not required to certify that the bank and its insured depository institution affiliates have received a rating of at least a satisfactory record of meeting community credit needs under the CRA. As specified in § 362.18(a)(2), an insured state nonmember bank is prohibited from commencing a new activity under section 46(a) or directly or indirectly acquiring control of a company as a financial subsidiary under section 46(a), if the state bank or any of the state bank's insured depository institution affiliates has received at each one's most recent examination a CRA rating of less than a satisfactory record of meeting community credit needs. The FDIC will monitor compliance with this CRA requirement at the time the new activity is commenced or control is acquired. Should the FDIC find that the bank or any of its insured depository institution affiliates is not in compliance with this CRA requirement, the FDIC will take appropriate action, including requiring divestiture.

As discussed above, one comment on the FDIC's interim final rule was that the agencies' rules should be uniform. Since the FDIC favors uniformity in rules as much as possible among the banking agencies, we considered whether the interim final rule's approach that required a 30-day advance notice process was the best way to implement section 46(a) or whether the OCC's self-certification process with a five-day advance notice or the FRB's approach, which requires a 15-day advance notice, would be preferable. After serious consideration of the comments and a careful evaluation of all of these approaches, the FDIC determined that conduct of as principal financial activities under section 46(a) can be adequately evaluated during the normal supervisory process. Thus, the final rule requires only that the bank file a certification prior to acquiring control of, or an interest in, a financial subsidiary that engages in section 46(a) financial activities as principal. A certification must also be filed prior to commencing a new as principal financial activity under section 46(a). The FDIC believes that this streamlined process will relieve regulatory burden and increase the predictability of regulatory compliance for insured state nonmember banks without sacrificing safety or soundness.

In the future, the FDIC will evaluate any section 46(a) activity by an insured state nonmember bank through the normal supervisory process.

The FDIC was asked to clarify the financial and operational safeguards requirement in § 362.18. The insured state nonmember bank and the financial subsidiary must comply with the financial and operational safeguards required by section 5136A(d) of the Revised Statutes. In the preamble to the interim rule, the FDIC stated that the OCC had not released any guidance or interpretations of these financial and operational safeguards, and there are still no guidelines from the OCC for the FDIC to evaluate. The FDIC has the authority to interpret this section as it is made applicable to state nonmember banks and their financial subsidiaries. Thus, the FDIC may relieve such banks and subsidiaries from any financial or operational safeguards that may be imposed by the OCC on national banks. The FDIC derives this authority from its independent interpretative and supervisory authority over state nonmember banks including the safety and soundness standards that govern state nonmember banks. The final rule now expressly provides a process for a state nonmember bank to seek such relief. Such determinations will be made by the FDIC on a case-by-case basis as it becomes aware of appropriate circumstances where the financial and operational safeguards applicable to national bank financial subsidiaries are not appropriate for state nonmember banks collectively or individually.

Section 362.18(c) provides that the bank must comply with the requirements of § 362.18(a) at the time of filing its certification and continue to comply with these requirements as long as the bank's subsidiary is engaged in financial activities. Section 362.18(f) also provides that the insured state nonmember bank and its insured depository institution affiliates must continue to comply with the requirements of § 362.18(d), unless the FDIC has granted an exception as set forth in § 362.18(e). If a bank or any of its insured depository institution affiliates fails to continue to meet the applicable requirements, then the FDIC may limit the bank's financial activities.

The FDIC believes that it has some discretion in this area since section 46 does not prescribe in detail what the FDIC must do should an insured state nonmember bank not be in compliance with the requirements. Section 5136A and new section 4(m) of the BHCA prescribe what the OCC and the FRB must do. In contrast, the statutory provisions do not prescribe how the FDIC should treat any such deficiencies. As a result, the FDIC will determine what is appropriate on a case-by-case basis.

Section 362.18(g) addresses subsidiaries covered under section 46(b), permitting insured nonmember state banks to retain their interests in subsidiaries lawfully held before the date of enactment of the G–L–B Act. The FDIC received one comment requesting that the final rule clearly state that any authorizations issued by the FDIC under section 24 prior to the adoption of subpart A of part 362 is covered by the grandfather provision. This clarification was made. Section 362.18(g)(1) provides that any insured state nonmember bank that began conducting an activity with the FDIC's approval under section 24 before such activity became subject to section 46(a) may continue to conduct the activity in compliance with the conditions and restrictions of the applicable section 24 order or regulation. In addition, any such state nonmember bank may submit an application to the FDIC for modification of any conditions the FDIC previously imposed in connection with such approval or imposed by regulation in association with notice-type approval for the activity. The FDIC interprets section 46 to invest the FDIC with retained section 24 jurisdiction over these activities. The FDIC draws this conclusion from two items in the G–L–B Act. First, the grandfather language in section 46(b) clearly authorizes state banks to retain pre-G–L–B Act subsidiaries and conduct pre-G–L–B Act activities through them, without also requiring the subsidiary to conduct the activity subject to conditions or restrictions in place as of the effective

date of the G–L–B Act. Second, the reservation of authority language in section 46(d) clearly states that the FDIC's authority to review subsidiary activities under section 24 is not superseded by anything in section 46.

As a separate matter, the FDIC has determined that the banks that are grandfathered to hold equity securities under section 24(f) may form new subsidiaries to engage in the grandfathered investment activity. Under the grandfathered authority provided by section 24(f), this activity is lawful for these banks at the bank level. As a result, subsidiaries established under this authority are exempt from the definition of financial subsidiary, as interpreted by both the FDIC and the FRB. Accordingly, banks that are grandfathered to hold equity securities under section 24(f) may form new subsidiaries to engage in the grandfathered investment activity.

The FDIC also has amended its notice processing rules to be consistent with part 303, subpart G to add references to the new certifications and applications required by the final rule.

Part 337

Section 337.4 Securities Activities of Insured State Nonmember Banks: Bank Transactions With Affiliated Securities Companies

On December 1, 1998, the FDIC proposed an amendment to subpart B that would have added safety and soundness guidelines to govern an insured state nonmember bank subsidiary which engages in the public sale, distribution or underwriting of stocks, bonds, debentures, notes or other securities activity that would be permissible for a subsidiary of a national bank but not permissible for a national bank directly.[7] These securities provisions were intended to address pending or approved applications under regulations issued by the OCC which permitted national banks to engage in certain activities through subsidiaries, even though the activities were not permissible for the national bank itself. Part 5 of the OCC's regulations governs operating subsidiaries. Former § 5.34(f), which confirmed that there could be activities not permissible for a national bank itself that could be conducted by an operating subsidiary, has been superseded and removed from the OCC's regulations. (65 FR 12905 (March 10, 2000)). Because of this change in the OCC's regulations and the fact that the G–L–B Act, through section 5136A of the Revised Statutes and section 46(a) of the FDI Act, established a new analytical framework, the FDIC will not be pursuing these amendments to subpart B.

The FDIC's proposal to amend subpart B also included a proposal to consolidate the remaining provisions of the FDIC's securities activities regulation found in § 337.4 into subpart B. The FDIC received two comments on this proposal, both of which expressed approval of eliminating § 337.4, and imposing less restrictive standards than those currently found in § 337.4. The FDIC has decided to finalize its proposal to eliminate § 337.4. Therefore, the FDIC is removing and reserving § 337.4.

Part 303

Section 303.120 Scope

Subpart G of part 303 contains the procedures for complying with the notice and application requirements of part 362 including the procedures for filing notices and applications described in subpart E of part 362. Subpart E of part 362 allows a state nonmember bank to file a notice and follow the FDIC's self-certification process if the bank chooses to engage in activities pursuant to section 46(a) of the FDI Act. The notice filing content and procedures in § 303.121(b) are unchanged for section 46(a) notices, but these notices will no longer be processed under § 303.122. In addition, § 303.120 provides the procedures for filing an application for relief from certain of the requirements contained in subpart E of part 362. These applications will continue to be processed under § 303.122(b).

Section 303.122 Processing

In paragraphs (a) and (b) of § 303.122, references to certain sections in part 362 have to be corrected because they were either inadvertently omitted or need to be deleted as a result of substantive changes to part 362. In § 303.122(a), a reference to § 362.3(a)(2)(iii)(A)(2) was inadvertently omitted. The substantive section, § 362.3(a)(2)(iii)(A)(2) references the expedited processing section. Thus, § 362.3(a)(2)(iii)(A)(2) is being added to the list of sections listed under § 303.122(a). Also, in § 303.122(a), because the substantive § 362.8(a)(2) is listed as one of those sections but is being removed from part 362, it is being removed from the list of sections listed under § 303.122(a).

In § 303.122(b), because §§ 362.5(b)(2) and 362.8(a)(2) are being removed from part 362, they also are being removed from the list of sections subject to the standard processing section under § 303.122(b). In addition, the reference to § 362.18(a) also will be removed because notices filed under that section would no longer be processed under § 303.122.

The delegations contained in § 303.123(b) are unchanged. This section continues to permit the review of notices and any additional supervisory follow-up to be handled at the regional offices.

Section 303.141 Filing Procedures

In paragraph (b)(1)(ii) of § 303.141, the language ''of part 362'' has been added to enhance the clarity of the reference to subparts C and D in that sentence.

Section 303.142 Processing

In paragraph (a) of § 303.142, because §§ 362.12(b)(2)(i) and 362.12(b)(4) are being removed from part 362, they also are being removed from the list of sections subject to the expedited processing section under § 303.142(a). In paragraphs (a) and (b) of § 303.142, references to certain sections in part 362 have to be corrected because they were incorrectly referenced. In paragraph (a) of § 303.142, the reference to § 362.11(b)(2)(i) was removed because it was inadvertently added. This change is consistent with § 362.11(b)(2)(i). In paragraph (b), the reference to § 362.11(a)(2) was incomplete and has been modified to add the paragraph (ii) to correspond to the substantive section, and the reference to § 362.11(b)(2) was incomplete and has been modified to add the paragraph (i) to correspond to the substantive section.

In paragraph (c) of § 303.142, ''insured state savings association'' has been replaced with ''insured savings association'' because some filings required under this section are made by federal savings associations. This change is consistent with the substantive section.

IV. Administrative Procedure Act

The FDIC will make this final rule effective immediately to permit state nonmember banks to immediately take advantage of the streamlined procedures and benefit from the regulatory burden relief that is found in this final rule. The interim final rule was effective as of March 11, 2000 because the FDIC found that it was impracticable to review public comments prior to the effective date of the interim final rule, and that there was good cause to make the interim rule effective on March 11, 2000, due to the fact that the rule set forth procedures to implement statutory changes that became effective on March 11, 2000. While the FDIC invited interested parties to comment on the rule at that time, the FDIC determined it would amend the rule as appropriate

[7] 63 FR 66339 (December 1, 1998).

after reviewing the comments. In addition in December 1998, the FDIC published a proposed amendment to part 362 on which the FDIC received and reviewed comments (63 FR 66339). This proposed amendment has not been the subject of final Board action. Accordingly, the FDIC reviewed the comments applicable to activities conducted under the new section 46 of the FDI Act and considered technical changes to subparts A and B with respect to activities conducted under section 24 of the FDI Act and subparts C and D with respect to activities conducted under section 28 and section 18(m) of the FDI Act that were necessitated by the new section 46. The FDIC finds that it may adopt an effective date that is less than 30 days after the date of publication in the **Federal Register** pursuant to the Administrative Procedure Act (5 U.S.C. 553(d)), because this rule removes restrictions and regulatory burden. Therefore, the regulation is effective upon publication. In addition, section 302 of the Riegle Community Development and Regulatory Improvement Act of 1994 [8] states that a final rule imposing new requirements must take effect on the first day of a calendar quarter following its publication. This rule does not impose new requirements; rather, depository institutions will be allowed to commence new activities immediately with no waiting period under the final rule. The FDIC finds that the final rule does not impose new reporting, disclosure or other requirements on insured depository institutions. Instead, this rule relieves burden and permits banks to engage in new activities in a more expedited fashion than was permitted under the interim rule. Thus, this final rule is effective immediately upon publication.

V. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), the FDIC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No comments were received explicitly about PRA issues in response to the interim final rule. The collection of information contained in this rule was submitted to OMB for review and approval in accordance with the PRA and has been approved under OMB control number 3064–0111, which expires on May 31, 2003. The FDIC continues to welcome comments about any of its collections of information. Please send comments to: Steven F. Hanft, Assistant Executive Secretary, Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street, N.W., Washington, DC.

VI. Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act, the FDIC certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The incidences in which insured state nonmember banks will be required to file a certification under the rule with respect to activities under the new section 46 of the FDI Act will be infrequent and will not require significant time to complete. Furthermore, the final rule streamlines requirements for insured state nonmember banks. It simplifies the requirements that apply when insured state nonmember banks conduct certain activities through subsidiaries. Whenever possible, the final rule clarifies the expectations of the FDIC when it requires filings to consent to activities by insured state banks. The final rule also will make it easier for smaller insured state nonmember banks to locate the rules that apply to their activities.

VII. Assessment of Impact of Federal Regulation on Families

The FDIC has determined that this regulation will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Pub. L. 105–277, 112 Stat. 2681).

VIII. Congressional Review Act

The OMB has determined that this final rule is not a ''major rule'' within the meaning of the Congressional Review Act (5 U.S.C. 801 *et seq.*). The FDIC will file the appropriate reports with Congress and the General Accounting Office so that this final rule can be reviewed.

List of Subjects

12 CFR Part 303

Administrative practice and procedure, Authority delegations (Government agencies), Banks, banking, Bank deposit insurance, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 337

Banks, banking, Reporting and recordkeeping requirements, Savings associations, Securities.

12 CFR Part 362

Administrative practice and procedure, Authority delegations (Government agencies), Bank deposit insurance, Banks, banking, Insured depository institutions, Investments, Reporting and recordkeeping requirements, Savings associations.

For the reasons set forth above and under the authority of 12 U.S.C. 1819(a)(Tenth), the interim final rule amending 12 CFR parts 303 and 362 which was published at 65 FR 15526 on March 23, 2000 is adopted as a final rule with changes and 12 CFR parts 303, 362, and 337 are amended to read as follows:

PART 303—FILING PROCEDURES AND DELEGATIONS OF AUTHORITY

1. The authority citation for part 303 continues to read as follows:

Authority: 12 U.S.C. 378, 1813, 1815, 1816, 1817, 1818, 1819 (Seventh and Tenth), 1820, 1823, 1828, 1828a, 1831a, 1831e, 1831o, 1831p–1, 1831w, 1835a, 1843(l), 3104, 3105, 3108; 3207; 15 U.S.C. 1601–1607.

2. Section 303.120 is revised to read as follows:

§ 303.120 Scope.

This subpart sets forth procedures for complying with notice and application requirements contained in subpart A of part 362 of this chapter, governing insured state banks and their subsidiaries engaging in activities which are not permissible for national banks and their subsidiaries. This subpart sets forth procedures for complying with notice and application requirements contained in subpart B of part 362 of this chapter, governing certain activities of insured state nonmember banks, their subsidiaries, and certain affiliates. This subpart also sets forth procedures for filing the notices and applications described in subpart E of part 362 of this chapter, governing subsidiaries of insured state nonmember banks engaging in financial activities.

3. In § 303.122, the first sentence of paragraph (a) and the first sentence of paragraph (b) are revised to read as follows:

§ 303.122 Processing.

(a) *Expedited processing.* A notice filed by an insured state bank seeking to commence or continue an activity under § 362.3(a)(2)(iii)(A)(2), § 362.4(b)(3)(i), or § 362.4(b)(5) of this chapter will be acknowledged in writing by the FDIC

[8] 12 U.S.C. 4802.

and will receive expedited processing, unless the applicant is notified in writing to the contrary and provided a basis for that decision. * * *

(b) *Standard processing for applications and notices that have been removed from expedited processing.* For an application filed by an insured state bank seeking to commence or continue an activity under § 362.3(a)(2)(iii)(A)(2), § 362.3(b)(2)(i), § 362.3(b)(2)(ii)(A), § 362.3(b)(2)(ii)(C), § 362.4(b)(1), § 362.4(b)(2), § 362.4(b)(4), § 362.8(b), or seeking a waiver or modification under § 362.18(e) or § 362.18(g)(3) of this chapter, or for notices which are not processed pursuant to the expedited processing procedures, the FDIC will provide the insured bank with written notification of the final action as soon as the decision is rendered. * * *

4. In § 303.141, paragraph (b)(1)(ii) is revised to read as follows:

§ 303.141 Filing procedures.

* * * * *

(b) * * *

(1) * * *

(ii) The amount of the association's existing or proposed direct or indirect investment in the activity as well as calculations sufficient to indicate compliance with any specific capital ratio or investment percentage limitation detailed in subpart C or D of part 362 of this chapter;

* * * * *

5. In § 303.142, the first sentence of paragraph (a), the first sentence of paragraph (b), and the first sentence of paragraph (c) are revised to read as follows:

§ 303.142 Processing.

(a) *Expedited processing.* A notice filed by an insured state savings association seeking to commence or continue an activity under § 362.11(b)(2)(ii) of this chapter will be acknowledged in writing by the FDIC and will receive expedited processing, unless the applicant is notified in writing to the contrary and provided a basis for that decision. * * *

(b) *Standard processing for applications and notices that have been removed from expedited processing.* For an application filed by an insured state savings association seeking to commence or continue an activity under § 362.11(a)(2)(ii), § 362.11(b)(2)(i), or § 362.12(b)(1) of this chapter or for notices which are not processed pursuant to the expedited processing procedures, the FDIC will provide the insured state savings association with written notification of the final action as soon as the decision is rendered. * * *

(c) *Notices of activities in excess of an amount permissible for a federal savings association; subsidiary notices.* Receipt of a notice filed by an insured savings association as required by § 362.11(b)(3) or § 362.15 of this chapter will be acknowledged in writing by the appropriate regional director (DOS). * * *

PART 337—UNSAFE AND UNSOUND BANKING PRACTICES

6. The authority citation for part 337 continues to read as follows:

Authority: 12 U.S.C. 375a(4), 375b, 1816, 1818(a), 1818(b), 1819, 1820(d)(10), 1821(f), 1828(j)(2), 1831, 1831f–1.

§ 337.4 [Removed and Reserved]

7. Section 337.4 is removed and reserved.

PART 362—ACTIVITIES OF INSURED STATE BANKS AND INSURED SAVINGS ASSOCIATIONS

8. The authority citation for part 362 is revised to read as follows:

Authority: 12 U.S.C. 1816, 1818, 1819(a)(Tenth), 1828(j), 1828(m), 1828a, 1831a, 1831e, 1831w, 1843(l).

9. In § 362.1, paragraph (c) is revised to read as follows:

§ 362.1 Purpose and scope.

* * * * *

(c) A subsidiary of an insured state bank may not engage in real estate investment activities that are not permissible for a subsidiary of a national bank unless the bank does so through a subsidiary of which the bank is a majority owner, is in compliance with applicable capital standards, and the FDIC has determined that the activity poses no significant risk to the appropriate deposit insurance fund. This subpart provides standards for majority-owned subsidiaries of insured state banks engaging in real estate investment activities that are not permissible for a subsidiary of a national bank.

* * * * *

10. In § 362.2, paragraph (r) is revised to read as follows:

§ 362.2 Definitions.

* * * * *

(r) *Subsidiary* means any company that is owned or controlled directly or indirectly by one or more insured depository institutions.

* * * * *

11. In § 362.4, paragraphs (b)(5)(ii) introductory text and (c)(2)(vi) are revised to read as follows:

§ 362.4 Subsidiaries of insured State banks.

* * * * *

(b) * * *

(5) * * *

(ii) *Securities activities.* Engage in the public sale, distribution or underwriting of securities that are not permissible for a national bank under section 16 of the Banking Act of 1933 (12 U.S.C. 24 Seventh), provided that the insured state nonmember bank lawfully controlled or acquired the subsidiary and had an approved notice or order from the FDIC prior to November 12, 1999 and provided that the following additional conditions are, and continue to be, met:

* * * * *

(c) * * *

(2) * * *

(vi) Has a majority of its board of directors who are neither directors nor executive officers of the state-chartered depository institution;

* * * * *

§ 362.5 [Amended]

13. In § 362.5, paragraphs (b)(1), (b)(2), and (b)(3) are removed and reserved.

14. Section 362.6 is revised to read as follows:

§ 362.6 Purpose and scope.

This subpart, along with the notice and application procedures in subpart G of part 303 of this chapter apply to certain banking practices that may have adverse effects on the safety and soundness of insured state nonmember banks. This subpart contains the required prudential separations between certain securities underwriting affiliates and insured state nonmember banks. The standards only will apply to affiliates of insured state nonmember banks that are not controlled by an entity that is supervised by a federal banking agency.

15. In § 362.7, paragraphs (a) and (b) are revised to read as follows:

§ 362.7 Definitions.

(a) *Affiliate* has the same meaning contained in section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813).

(b) *Activity, company, control, equity security, insured state nonmember bank, security and subsidiary* have the same meaning as provided in subpart A of this part.

16. Section 362.8 is revised to read as follows:

§ 362.8 Restrictions on activities of insured state nonmember banks affiliated with certain securities companies.

(a) The FDIC has found that an unrestricted affiliation between an insured state nonmember bank and certain companies may have adverse effects on the safety and soundness of insured state nonmember banks.

(b) An insured state nonmember bank is prohibited from becoming or remaining affiliated with any securities underwriting affiliate company that directly engages in the public sale, distribution or underwriting of stocks, bonds, debentures, notes, or other securities activity, of a type not permissible for a national bank directly, unless the company is controlled by an entity that is supervised by a federal banking agency or the state nonmember bank submits an application in compliance with § 303.121 of this chapter and the FDIC grants its consent under the procedure in § 303.122(b) of this chapter, or the state nonmember bank and the securities underwriting affiliate company comply with the following requirements:

(1) The securities business of the affiliate is physically separate and distinct in its operations from the operations of the bank, provided that this requirement shall not be construed to prohibit the bank and its affiliate from sharing the same facility if the area where the affiliate conducts retail sales activity with the public is physically distinct from the routine deposit taking area of the bank;

(2) The affiliate conducts business pursuant to independent policies and procedures designed to inform customers and prospective customers of the affiliate that the affiliate is a separate organization from the bank and the state-chartered depository institution is not responsible for and does not guarantee the obligations of the affiliate;

(3) The bank adopts policies and procedures, including appropriate limits on exposure, to govern its participation in financing transactions underwritten by an underwriting affiliate;

(4) The bank does not express an opinion on the value or the advisability of the purchase or sale of securities underwritten or dealt in by an affiliate unless it notifies the customer that the entity underwriting, making a market, distributing or dealing in the securities is an affiliate of the bank; and

(5) The bank complies with the investment and transaction limitations in sections 23A and 23B of the Federal Reserve Act (12 U.S.C. 371c and 371c–1) with respect to the affiliate.

17. In § 362.10, paragraph (a) is revised to read as follows:

§ 362.10 Definitions.

* * * * *

(a) *Affiliate* has the same meaning as provided in subpart B of this part.

* * * * *

18. In § 362.12, paragraphs (b)(2)(i) and (b)(4) are removed and reserved, the paragraph (c) heading ''Investments and transaction limits.'' is italicized, and paragraph (b)(1) is amended by adding a new sentence at the end to read as follows:

§ 362.12 Service corporations of insured State savings associations.

* * * * *

(b) * * *

(1) * * * The activities covered by this paragraph may include, but are not limited to, acquiring and retaining equity securities of a company engaged in the public sale distribution or underwriting of securities.

* * * * *

19. Subpart E is revised to read as follows:

Subpart E—Financial Subsidiaries of Insured State Nonmember Banks

Sec.

Subpart E—Financial Subsidiaries of Insured State Nonmember Banks

§ 362.16 Purpose and scope.

(a) This subpart, along with the notice and application procedures in subpart G of part 303 of this chapter, implements section 46 of the Federal Deposit Insurance Act (12 U.S.C. 1831w) and requires that an insured state nonmember bank certify certain facts and file a notice with the FDIC before the insured state nonmember bank may control or hold an interest in a financial subsidiary under section 46(a) of the Federal Deposit Insurance Act. This subpart also implements the statutory Community Reinvestment Act (CRA) (12 U.S.C. 2901 *et seq.*) requirement set forth in subsection (4)(l)(2) of the Bank Holding Company Act (12 U.S.C. 1843(l)(2)), which is applicable to state nonmember banks that commence new activities through a financial subsidiary or directly or indirectly acquire control of a company engaged in an activity under section 46(a).

(b) This subpart does not cover activities conducted other than ''as principal''. For purposes of this subpart, activities conducted other than ''as principal'' are defined as activities conducted as agent for a customer, conducted in a brokerage, custodial, advisory, or administrative capacity, or conducted as trustee, or in any substantially similar capacity. For example, this subpart does not cover acting solely as agent for the sale of insurance, securities, real estate, or travel services; nor does it cover acting as trustee, providing personal financial planning advice, or safekeeping services.

§ 362.17 Definitions.

For the purposes of this subpart, the following definitions will apply:

(a) *Activity, company, control, insured depository institution, insured state bank, insured state nonmember bank and subsidiary* have the same meaning as provided in subpart A of this part.

(b) *Affiliate* has the same meaning provided in subpart B of this part.

(c) *Financial subsidiary* means any company that is controlled by one or more insured depository institutions other than:

(1) A subsidiary that only engages in activities that the state nonmember bank is permitted to engage in directly and that are conducted on the same terms and conditions that govern the conduct of the activities by the state nonmember bank; or

(2) A subsidiary that the state nonmember bank is specifically authorized to control by the express terms of a federal statute (other than section 46(a) of the Federal Deposit Insurance Act (12 U.S.C. 1831w)), and not by implication or interpretation, such as the Bank Service Company Act (12 U.S.C. 1861 *et seq.*).

(d) *Tangible equity and Tier 2 capital* have the same meaning as set forth in part 325 of this chapter.

(e) *Well-managed* means:

(1) Unless otherwise determined in writing by the appropriate federal banking agency, the institution has received a composite rating of 1 or 2 under the Uniform Financial Institutions Rating System (or an equivalent rating under an equivalent rating system) in connection with the most recent state or federal examination or subsequent review of the depository institution and at least a rating of 2 for management, if such a rating is given; or

(2) In the case of any depository institution that has not been examined by its appropriate federal banking agency, the existence and use of managerial resources that the appropriate federal banking agency determines are satisfactory.

§ 362.18 Financial subsidiaries of insured state nonmember banks.

(a) *''As principal'' activities.* An insured state nonmember bank may not

obtain control of or hold an interest in a financial subsidiary that engages in activities as principal or commence any such new activity pursuant to section 46(a) of the Federal Deposit Insurance Act (12 U.S.C. 1831w) unless the insured state nonmember bank files a notice containing the information required in § 303.121(b) of this chapter and certifies that:

(1) The insured state nonmember bank is well-managed;

(2) The insured state nonmember bank and all of its insured depository institution affiliates are well-capitalized as defined in the appropriate capital regulation and guidance of each institution's primary federal regulator; and

(3) The insured state nonmember bank will deduct the aggregate amount of its outstanding equity investment, including retained earnings, in all financial subsidiaries that engage in activities as principal pursuant to section 46(a) of the Federal Deposit Insurance Act (12 U.S.C. 1831w), from the bank's total assets and tangible equity and deduct such investment from its total risk-based capital (this deduction shall be made equally from Tier 1 and Tier 2 capital).

(b) *Community Reinvestment Act (CRA).* An insured state nonmember bank may not commence any new activity subject to section 46(a) of the Federal Deposit Insurance Act (12 U.S.C. 1831w) or directly or indirectly acquire control of a company engaged in any such activity pursuant to § 362.18(a)(1), if the bank or any of its insured depository institution affiliates received a CRA rating of less than ''satisfactory record of meeting community credit needs'' in its most recent CRA examination.

(c) *Other requirements.* An insured state nonmember bank controlling or holding an interest in a financial subsidiary under section 46(a) of the Federal Deposit Insurance Act (12 U.S.C. 1831w) must meet and continue to meet the requirements set forth in paragraph (a) of this section as long as the insured state nonmember bank holds the financial subsidiary and:

(1) Disclose and continue to disclose the capital separation required in paragraph (a)(3) in any published financial statements;

(2) Comply and continue to comply with sections 23A and 23B of the Federal Reserve Act (12 U.S.C. 371c and 371c–1) as if the subsidiary were a financial subsidiary of a national bank; and

(3) Comply and continue to comply with the financial and operational standards provided by section 5136A(d) of the Revised Statutes of the United States (12 U.S.C. 24A(d)), unless otherwise determined by the FDIC.

(d) *Securities underwriting.* If the financial subsidiary of the insured state nonmember bank will engage in the public sale, distribution or underwriting of stocks, bonds, debentures, notes, or other securities activity of a type permissible for a national bank only through a financial subsidiary, then the state nonmember bank and the financial subsidiary also must comply and continue to comply with the following additional requirements:

(1) The securities business of the financial subsidiary must be physically separate and distinct in its operations from the operations of the bank, provided that this requirement shall not be construed to prohibit the bank and its financial subsidiary from sharing the same facility if the area where the financial subsidiary conducts securities business with the public is physically distinct from the routine deposit taking area of the bank;

(2) The financial subsidiary must conduct its securities business pursuant to independent policies and procedures designed to inform customers and prospective customers of the financial subsidiary that the financial subsidiary is a separate organization from the insured state nonmember bank and that the insured state nonmember bank is not responsible for and does not guarantee the obligations of the financial subsidiary;

(3) The bank must adopt policies and procedures, including appropriate limits on exposure, to govern its participation in financing transactions underwritten by its financial subsidiary; and

(4) The bank must not express an opinion on the value or the advisability of the purchase or sale of securities underwritten or dealt in by its financial subsidiary unless the bank notifies the customer that the entity underwriting, making a market, distributing or dealing in the securities is a financial subsidiary of the bank.

(e) *Applications for exceptions to certain requirements.* Any insured state nonmember bank that is unable to comply with the well-managed requirement of § 362.18(a)(1) and (c)(1), any state nonmember bank that has appropriate reasons for not meeting the financial and operational standards applicable to a financial subsidiary of a national bank conducting the same activities as provided in § 362.18(c)(3) or any state nonmember bank and its financial subsidiary subject to the securities underwriting activities requirements in § 362.18(d) that is unable to meet such requirements may submit an application in compliance with § 303.121 of this chapter to seek a waiver or modification of such requirements under the procedure in § 303.122(b) of this chapter. The FDIC may impose additional prudential safeguards as are necessary as a condition of its consent.

(f) *Failure to meet requirements.* (1) *Notification by FDIC.* The FDIC will notify the insured state nonmember bank in writing and identify the areas of noncompliance, if:

(i) The FDIC finds that an insured state nonmember bank or any of its insured depository institution affiliates is not in compliance with the CRA requirement of § 362.18(b) at the time any new activity is commenced or control of the financial subsidiary is acquired;

(ii) The FDIC finds that the facts to which an insured state nonmember bank certified under § 362.18(a) are not accurate in whole or in part; or

(iii) The FDIC finds that the insured state nonmember bank or any of its insured depository institution affiliates or the financial subsidiary fails to meet or continue to comply with the requirements of § 362.18(c) and (d), if applicable, and the FDIC has not granted an exception under the procedures set forth in § 362.18(e) and in § 303.122(b) of this chapter.

(2) *Notification by state nonmember bank.* An insured state nonmember bank that controls or holds an interest in a financial subsidiary must promptly notify the FDIC if the bank becomes aware that any depository institution affiliate of the bank has ceased to be well-capitalized.

(3) *Subsequent action by FDIC.* The FDIC may take any appropriate action or impose any limitations, including requiring that the insured state nonmember bank to divest control of any such financial subsidiary, on the conduct or activities of the insured state nonmember bank or any financial subsidiary of the insured state bank that fails to:

(i) Meet the requirements listed in § 362.18(a) and (b) at the time that any new section 46 activity is commenced or control of a financial subsidiary is acquired by an insured state nonmember bank; or

(ii) Meet and continue to meet the requirements listed in § 362.18(c) and (d), as applicable.

(g) *Coordination with section 24 of the Federal Deposit Insurance Act.* (1) *Continuing authority under section 24.* Notwithstanding § 362.18(a) through (f), an insured state bank may retain its interest in any subsidiary:

(i) That was conducting a financial activity with authorization in accordance with section 24 of the Federal Deposit Insurance Act (12 U.S.C. 1831a) and the applicable implementing regulation found in subpart A of this part 362 before the date on which any such activity became for the first time permissible for a financial subsidiary of a national bank; and

(ii) Which insured state nonmember bank and its subsidiary continue to meet the conditions and restrictions of the section 24 order or regulation approving the activity as well as other applicable law.

(2) *Continuing authority under section 24(f) of the Federal Deposit Insurance Act.* Notwithstanding § 362.18(a) through (f), an insured state bank with authority under section 24(f) of the Federal Deposit Insurance Act (12 U.S.C. 1831a(f)) to hold equity securities may continue to establish new subsidiaries to engage in that investment activity.

(3) *Relief from conditions.* Any state nonmember bank that meets the requirements of paragraph (g)(1) of this section or that is subject to section 46(b) of the Federal Deposit Insurance Act (12 U.S.C. 1831w(b)) may submit an application in compliance with § 303.121 of this chapter and seek the consent of the FDIC under the procedure in § 303.122(b) of this chapter for modification of any conditions or restrictions the FDIC previously imposed in connection with a section 24 order or regulation approving the activity.

(4) *New financial subsidiaries.* Notwithstanding subpart A of this part 362, an insured state bank may not, on or after November 12, 1999, acquire control of, or acquire an interest in, a financial subsidiary that engages in activities as principal or commences any new activity under section 46(a) of the Federal Deposit Insurance Act (12 U.S.C. 1831w) other than as provided in this section.

By order of the Board of Directors.

Dated at Washington, D.C. this 21st day of December, 2000.

Federal Deposit Insurance Coporation.

James D. LaPierre,

Deputy Executive Secretary.

[FR Doc. 01–175 Filed 1–4–01; 8:45 am]

BILLING CODE 6714–14–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–214–AD; Amendment 39–12064; AD 2000–26–14]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A310 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all Airbus Model A310 series airplanes, that requires repetitive detailed visual inspections to detect cracks propagating from the fastener holes that attach the left-and right-hand pick-up angles at frame 40 to the wing lower skin and fuselage panel, and corrective actions, if necessary. The actions specified by this AD are intended to prevent reduced structural integrity of the airplane due to fatigue damage and consequent cracking of the pick-up angles at frame 40. This action is intended to address the identified unsafe condition.

DATES: Effective February 9, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 9, 2001.

ADDRESSES: The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all Airbus Model A310 series airplanes was published in the **Federal Register** on October 25, 2000 (65 FR 63817). That action proposed to require repetitive detailed visual inspections to detect cracks propagating from the fastener holes that attach the left- and right-hand pick-up angles at frame 40 to the wing lower skin and fuselage panel, and corrective actions, if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

The FAA estimates that 47 airplanes of U.S. registry will be affected by this AD, that it will take approximately 2 work hours per airplane to accomplish the required inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of this AD on U.S. operators is estimated to be $5,640, or $120 per airplane, per inspection cycle.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory

Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2000–26–14 Airbus Industrie: Amendment 39–12064. Docket 2000–NM–214–AD.

Applicability: All Model A310 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (g) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent reduced structural integrity of the airplane due to fatigue damage and consequent cracking of the pick-up angles at frame 40, accomplish the following:

Inspections and Corrective Actions

(a) Perform a detailed visual inspection to detect cracks propagating from the fastener holes that attach the left- and right-hand pick-up angles at frame 40 to the wing lower skin and fuselage panel, at the time specified in paragraph (b), (c), (d), (e) or (f) of this AD, as applicable. Perform the actions in accordance with Figure 2, Sheet 1, ''Synoptic Chart,'' of Airbus Service Bulletin A310–53A2111, Revision 01, dated June 21, 2000.

(1) If no cracking is found during the inspection required by paragraph (a) of this AD, repeat the detailed visual inspection thereafter at the interval specified in paragraph (a)(1)(i) or (a)(1)(ii) of this AD, as applicable.

(i) For Model A310–200 series airplanes: Except as provided by paragraph (d) of this AD, repeat the inspection thereafter at intervals not to exceed 1,000 flight cycles or 2,600 flight hours, whichever occurs first.

(ii) For Model A310–300 series airplanes: Except as provided by paragraph (d) of this AD, repeat the inspection thereafter at intervals not to exceed 850 flight cycles or 2,800 flight hours, whichever occurs first.

(2) If any cracking is found during the inspection required by paragraph (a) of this AD, prior to further flight, perform applicable corrective actions [including repair (drilling and reaming a crack stop hole in the pick-up angle, performing a Rototest inspection and repetitive detailed visual inspections at the time specified in the service bulletin, and replacing the pick-up angle with a new angle at the time specified in the service bulletin); or immediate replacement of any cracked angle with a new angle]. Perform the actions and repetitive inspections in accordance with Figure 2, Sheet 1, ''Synoptic Chart,'' of Airbus Service Bulletin A310–53A2111, Revision 01, dated June 21, 2000.

Note 2: Accomplishment of the actions required by paragraph (a) of this AD in accordance with Airbus Service Bulletin A310–53A2111, dated April 21, 2000, is considered to be acceptable for compliance with the requirements of that paragraph.

Compliance Times

(b) For Model A310–200 series airplanes: Except as provided by paragraphs (d), (e), and (f) of this AD, perform the initial inspection at the later of the times specified in paragraphs (b)(1) and (b)(2) of this AD.

(1) Prior to the accumulation of 7,900 total flight cycles or 23,600 total flight hours, whichever occurs first.

(2) Within 700 flight cycles or 1,200 flight hours after the effective date of this AD, whichever occurs first.

(c) For Model A310–300 series airplanes: Except as provided by paragraphs (d), (e), and (f) of this AD, perform the initial inspection required by paragraph (a) of this AD at the later of the times specified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Prior to the accumulation of 6,700 total flight cycles or 24,700 total flight hours, whichever occurs first.

(2) Within 700 flight cycles or 1,200 flight hours after the effective date of this AD, whichever occurs first.

(d) For airplanes that have accumulated more than 18,000 total flight cycles or 53,000 total flight hours as of the effective date of this AD: Perform the initial inspection required by paragraph (a) of this AD within 350 flight cycles or 600 flight hours after the effective date of this AD, whichever occurs first. Repeat the inspection thereafter at intervals not to exceed 350 flight cycles or 600 flight hours, whichever occurs first.

(e) For airplanes having manufacturer's serial number 0162 through 0326 inclusive, on which Airbus Service Bulletin A310–53–2014 has been accomplished prior to the effective date of this AD: The initial inspection threshold may be counted from the date of accomplishment of Airbus Service Bulletin A310–53–2014.

(f) For airplanes on which a pick-up angle has been replaced: For that pick-up angle only, the initial inspection threshold may be counted from the date of installation of the new pick-up angle.

Note 3: For the purposes of this AD, a detailed visual inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Alternative Methods of Compliance

(g) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(h) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(i) The actions shall be done in accordance with Airbus Service Bulletin A310–53A2111, Revision 01, including Appendix 1, dated June 21, 2000. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 5: The subject of this AD is addressed in French airworthiness directive 2000–209–310(B), dated June 14, 2000.

Effective Date

(j) This amendment becomes effective on February 9, 2001.

Issued in Renton, Washington, on December 22, 2000.

John J. Hickey,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–28 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–ASO–35]

Amendment of Class D and Class E4 Airspace; Gainesville, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects an error in the geographic position coordinates of a final rule that was published in the **Federal Register** on November 13, 2000, (65 FR 67624), Airspace Docket No. 00–ASO–35. The final rule amended Class D and Class E4 airspace at Gainesville, FL.

EFFECTIVE DATE: January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Wade T. Carpenter, Jr., Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5586.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 00–28989, Airspace Docket No. 00–ASO–35, published on November 13, 2000, (65 FR 67624), amended Class D and Class E4 airspace at Gainesville, FL. The airspace description inadvertently contained incorrect geographic position coordinates for the GATORS VORTAC. This action corrects the error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the airspace description for the Class E4 airspace area Gainesville, FL, incorporated by reference at Sec. 71–1 and published in the **Federal Register** on November 13, 2000 (65 FR 67624), is corrected as follows:

§ 71.71 [Corrected]

* * * * *

ASO FL E4 Gainesville, FL [Corrected]

On page 67625, column 2, line 2 of the GATORS VORTAC geographic position description, correct the geographic position coordinates by substituting ''(lat. 29°41′11″N, long. 82°16′28″W)'' for ''(lat 29°34′20″N, long. 82°21′45″W)''.

* * * * *

Dated: Issued in College Park, Georgia, on December 7, 2000.

Wade T. Carpenter,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 01–348 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 3532]

RIN 1400–AA48

Bureau of Consular Affairs; Visas: Aliens Ineligible to Transit Without Visas (TWOV)

AGENCY: Bureau of Consular Affairs, Department of State.

ACTION: Interim rule with request for comments.

SUMMARY: Section 212(d)(4)(A) of the Immigration and Nationality Act (INA) permits the Secretary of State, acting jointly with the Attorney General, to waive the visa and passport requirement of INA 212(a)(7)(B) for certain aliens in direct transit through the United States. This waiver allows an alien to transit the United States without a passport and visa provided the alien is traveling on a carrier signatory to an agreement with the Immigration and Naturalization Service (INS) in accordance with INA 233(c) and bears documentation establishing identity and nationality which permits the alien's entry into another country. This rule sets forth a new list of countries that are ineligible to transit without visa (TWOV).

DATES: *Effective Date:* This interim rule is effective February 5, 2001.

Comment Date: Interested persons should submit comments on or before March 6, 2001.

ADDRESSES: Submit comments, in duplicate, to the Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20522–0113.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Office, Room L603–C, SA–1, Department of State, Washington, DC 20520–0106, (202) 663–1204; or e-mail: *odomhe@state.gov.*

SUPPLEMENTARY INFORMATION:

What Is the Authority for Allowing or Prohibiting Transit Without Visa?

Section 212(d)(4)(C) of the Immigration and Nationality Act (INA) provides the authority for the Secretary of State, acting jointly with the Attorney General, to waive the passport and/or visa requirement for a nonimmigrant who is in immediate and continuous transit through the United States and is using a carrier that has entered into a Transit Without Visa (TWOV) Agreement as provided in INA 233(c)

Who Determines Which Countries Can Transit Without a Visa?

Since TWOV does not involve the issuance of a visa, the Department's role in the day-to-day administration of the TWOV program is minimal. Therefore, the Department's regulation at 22 CFR 41.2(i), for the most part, is merely a restatement of the INS regulation on the same subject. The Department does become involved, however, in the designation of those countries whose citizens are ineligible to utilize the TWOV. The current regulation provides a list of ineligible countries.

Interim Rule

How Will the Department of State Amend its Regulations?

This rule, and the INS rule published elsewhere in this issue, amends the list of countries which the Department and the INS have determined are not eligible for this transit without visa (TWOV) program.

The Department has also dropped from the regulation the list of countries whose citizens were eligible to TWOV solely on the basis of reciprocity. A separate list of such countries is no longer deemed necessary and thus will no longer be maintained. Rather a single list of countries whose citizens have been denied TWOV privileges will be published.

The Department is also amending the reference to ''INA 238(d)'' to read ''INA 233''.

Which Countries Will Benefit From This Amendment?

Due to the breakup of the former Soviet Union, citizens of Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan are now eligible to TWOV. Because of the democratization of the former Warsaw Pact countries, citizens of Albania, Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania and Slovakia may also TWOV. The TWOV privilege is also extended to citizens of Croatia, the

Former Yugoslav Republic of Macedonia and Slovenia, formerly part of the Socialist Federal Republic of Yugoslavia.

Which Countries Are Added to the List of Countries Whose Citizens Cannot TWOV?

The rule adds Angola, Belarus, Burma, Burundi, Central African Republic, People's Republic of China, Congo (Brazzaville), Nigeria, Russia, Sierra Leone, Somalia and Sudan to the list of countries whose citizens cannot TWOV.

What Criteria Is Used To Determine Ineligibility to TWOV?

In determining which countries may or may not TWOV, the Department (in conjunction with the INS) takes into consideration such things as:

(1) Abuse of the TWOV privilege;

(2) Nonimmigrant visa refusal rates;

(3) The stability of the country;

(4) Whether citizens of the country are linked to terrorist activity, narcotics trafficking; or international criminal activity;

(5) Any Presidential proclamation restricting the entry of the country's citizens; and

(6) Security concerns.

Based on a review of these and other relevant factors, the Department and the INS will determine the countries whose citizens will not be eligible to TWOV. The agencies will periodically review the list to determine whether countries should be added or removed.

Administrative Procedure Act

The Department is implementing this rule as an interim rule, with a 60-day provisions for post-promulgation public comments, based on the ''good cause'' exceptions found at 5 U.S.C. 553(b)(B) and 553(d)(3). The Department considers this rule to be beneficial to the general public since it extends the TWOV privilege to citizens of several additional countries. In addition, this rule grants and recognizes an exemption or relief from restrictions within the scope of 5 U.S.C. 5553(d)(1). The Department finds it necessary to implement this rule effective immediately to minimize abuse of the TWOV privilege.

Regulatory Flexibility Act

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

The Department of State does not consider this rule, to be a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, and the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping requirements. The information collection requirement (Form OF–156) contained by reference in this rule was previously approved for use by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

List of Subjects in 22 CFR Part 41

Aliens, Nonimmigrants, Passports and visas.

In view of the foregoing, the Department amends 22 CFR as follows:

PART 41—[AMENDED]

1. The authority citation continues to read as follows:

Authority: 8 U.S.C. 1104; Pub. L. 105–277, 112 Stat. 2681 *et. seq.*

2. Section 41.2 is amended by revising paragraph (i) to read as follows:

§ 41.2 Waiver by Secretary of State and Attorney General of passport and/or visa requirements for certain categories of nonimmigrants.

* * * * *

(i) *Aliens in immediate transit without visa (TWOV).* (1) An alien in immediate and continuous transit through the United States is not required to be in possession of a passport or visa if:

(i) The carrier transporting the alien has signed an agreement with the Immigration and Naturalization Service (INS) pursuant to the provisions of INA 233(c); and

(ii) The alien is en route to a specified foreign country; and

(iii) The alien possesses documentation establishing identity, nationality, and the ability to enter a country other than the United States.

(2) Notwithstanding the provisions of paragraph (i)(1) of this section, this waiver is not available to an alien who is a citizen of: Afghanistan, Angola, Bangladesh, Belarus, Bosnia-Herzegovina, Burma, Burundi, Central African Republic, People's Republic of China, Congo (Brazzaville), India, Iran, Iraq, Libya, Nigeria, North Korea, Pakistan, Russia, Serbia, Sierra Leone, Somalia, Sri Lanka, Sudan.

Dated: September 15, 2000.

Maura Harty,

Acting Assistant Secretary for Consular Affairs.

[FR Doc. 01–356 Filed 1–4–01; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8926]

RIN 1545–AX62

Prevention of Abuse of Charitable Remainder Trusts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document finalizes regulations that modify the application

of the rules governing the character of certain distributions from a charitable remainder trust. These regulations are necessary to prevent taxpayers from using charitable remainder trusts to achieve inappropriate tax avoidance. The regulations affect charitable remainder trusts described in section 664 and certain beneficiaries of those trusts.

EFFECTIVE DATES: These regulations are effective January 5, 2001. For dates of applicability of these regulations, see §§ 1.643(a)–8(d), 1.664–2(a)(1)(i)(*e*), and 1.664–3(a)(1)(i)(*l*).

FOR FURTHER INFORMATION CONTACT: Catherine Moore (202) 622–3070.

SUPPLEMENTARY INFORMATION:

Background

On October 18, 1999, proposed regulations (REG–116125–99) to amend §§ 1.643(a)–8 and 1.664–1 of the Income Tax Regulations (26 CFR Part 1) were published in the **Federal Register** (64 FR 56718). Several written comments were received in response to the notice of proposed rulemaking, and a public hearing was held on February 9, 2000. After considering all the comments, the proposed regulations under sections 643 and 664 are adopted as revised by this Treasury decision. The comments received and the revisions made are discussed below.

Explanation of Provisions and Summary of Comments

I. General Background

The proposed regulations were issued in response to certain abusive transactions that attempt to use a section 664 charitable remainder trust to convert appreciated assets into cash while avoiding tax on the gain from the disposition of the assets. In these abusive transactions, a taxpayer typically contributes highly appreciated assets to a charitable remainder trust having a relatively short term and a relatively high payout rate. Rather than sell the assets to obtain cash to pay the annuity or unitrust amount to the beneficiary, the trustee borrows money, enters into a forward sale of the assets, or engages in some similar transaction. The borrowing, forward sale, or other similar transaction does not result in current income to the trust; thus, the parties attempt to characterize the distribution of cash to the beneficiary as a tax-free return of corpus under section 664(b)(4). The proposed regulations provide that, in this situation, the trust shall be treated as having sold a pro rata portion of the trust assets.

II. Public Comments

One commentator argued that the transactions targeted by the regulations are not abusive because they comply with the statutory changes made to section 664 by the Taxpayer Relief Act of 1997 (1997 Act), Public Law 105–34, 111 Stat. 788 (1997). Those statutory changes require that the annual payout rate to noncharitable beneficiaries not exceed 50 percent of the value of the property contributed to the charitable remainder trust and that the actuarial value of the charity's remainder interest be not less than 10 percent of the value of such property. Although the charitable remainder trusts involved in transactions targeted by the proposed regulations are drafted to comply with these statutory changes, the transactions result in the same kind of abuse that Congress was concerned about in the 1997 Act. It does not follow that because Congress did not anticipate in 1997 this latest abuse that Congress intended to allow it.

In the legislative history to the 1997 Act, Congress labeled the accelerated charitable remainder trusts it was targeting as ''abusive and * * * inconsistent with the purpose of the charitable remainder trust rules.'' S. Rep. No. 33, 105th Cong., 1st Sess. 201 (1997). Congress noted the efforts of the Treasury Department and the IRS to combat abuse in the area through issuing proposed regulations in 1997, stating:

> The Committee intends that the provision of the Committee bill does not limit or alter the validity of regulations proposed by the Treasury Department on April 18, 1997, or the Treasury Department's authority to address this or other abuses of the rules governing the taxation of charitable remainder trusts or their beneficiaries.

S. Rep. No. 33 at 201. Thus, Congress has neither prohibited nor discouraged further regulatory activity in the charitable remainder trust area. To the contrary, based on the legislative history to the 1997 Act, Congress intended the Treasury Department to continue to take all necessary action to prevent abuses in this area.

Several commentators questioned the authority to issue the regulations under section 643(a)(7). Two commentators maintained that the proposed regulations overstep the bounds of administrative rulemaking in that section 643(a)(7) was enacted along with the foreign trust provisions of the Small Business Job Protection Act of 1996 (SBJP Act), Public Law 104–88, 110 Stat. 1755 (1996), and therefore applies only to foreign trusts. One commentator, citing the introductory clause of section 664(a), ''[n]otwithstanding any other provision of this subchapter,'' argued that the Treasury Department and the IRS are prohibited from applying section 643(a)(7) to charitable remainder trusts. Some commentators maintained that section 643(a)(7) does not authorize the promulgation of regulations imposing a deemed sale where no actual sale has occurred. These commentators implied that regulatory authority under section 643(a)(7) should be limited to the concept of distributable net income (DNI). The Treasury Department and the IRS disagree with these views.

Although the SBJP Act included dramatic changes in the foreign trust area, the trust anti-abuse rule was not limited to foreign trusts and in fact contains no reference to foreign trusts. Furthermore, the Treasury Department and the IRS believe that Congress put the anti-abuse rule in section 643 because that section contains the rules applicable to all of Part 1 of Subchapter J of the Internal Revenue Code. Section 643(a)(7) gives the Secretary of the Treasury the authority to ''prescribe such regulations as may be necessary or appropriate to carry out the purposes of this *part,* including regulations to prevent avoidance of such purposes'' (emphasis added). ''Part'' in this context refers to Part 1 of Subchapter J and encompasses sections 641 through 685, including section 664 governing charitable remainder trusts. The legislative history to the SBJP Act clarifies that the anti-abuse rule is not limited to foreign trusts or the DNI rules. The House Conference Report states:

> [The rule] authorizes the Secretary of the Treasury to issue regulations, on or after the date of enactment, that may be necessary or appropriate to carry out the purposes of the rules applicable to estates, trusts, and beneficiaries, including regulations to prevent the avoidance of those purposes.

H.R. Conf. Rep. No. 737, 104th Cong., 2d Sess. 335 (1996).

In addition, the plain language of section 664(a) does not prohibit the promulgation of regulations that apply section 643(a)(7) to abusive charitable remainder trust transactions. Section 664(a) states in full:

> Notwithstanding any other provision of this subchapter, the provisions of this section shall, in accordance with regulations prescribed by the Secretary, apply in the case of a charitable remainder annuity trust and a charitable remainder unitrust.

This language provides that the provisions of section 664 apply in the case of a charitable remainder annuity trust and charitable remainder unitrust. The Treasury Department and the IRS,

however, do not view this language as providing that no other provisions of subchapter J can apply in the case of abusive charitable remainder trust transactions. Applying these regulations to abusive charitable remainder trust transactions does not conflict with or override the provisions of section 664. Accordingly, the Treasury Department and the IRS believe that the plain language of section 664(a) does not prohibit promulgation of these regulations.

After considering the comments questioning the authority to promulgate and finalize the proposed regulations, the Treasury Department and the IRS have concluded that the regulations are an appropriate exercise of their regulatory authority and are authorized by the regulatory authority granted to them under section 643(a)(7) and 664(a).

Another commentator, while supporting the proposed regulations in general, suggested that the regulations contain a more precise definition of the targeted abuse. In response to this comment, the stated purpose in § 1.643(a)–8(a) has been modified to include a specific reference to the rules regarding the characterization of distributions from charitable remainder trusts in the hands of the recipients.

That same commentator requested clarification of whether a deemed sale by a charitable remainder trust under § 1.643(a)–8(b) would generate unrelated business taxable income (UBTI) within the meaning of section 512. Section 664(c) provides that whether a charitable remainder trust has UBTI for any taxable year, and thus is subject to tax for that year, is determined under the normal rules of sections 512, 513, and 514. The proposed regulations do not affect this general rule. However, an example in the final regulations clarifies that, to the extent that a borrowing by a charitable remainder trust is recharacterized as a deemed sale by the trust under § 1.643(a)–8(b), the borrowing is not ''acquisition indebtedness'' within the meaning of section 514(c).

Another commentator suggested eliminating the provisions in §§ 1.664–2(a)(1)(i)(a) and 1.664–3(a)(1)(i)(g) of the regulations requiring that the annuity amount or the fixed percentage unitrust amount generally be paid by the end of the year for which it is due. That commentator contended that the payment rule is no longer necessary in light of the proposed regulations.

The Treasury Department and the IRS believe that the proposed regulations serve a function different from the payment rule. The proposed regulations seek to eliminate tax-free distributions from charitable remainder trusts due to manipulation of the character of distributions from those trusts. The payment rule, on the other hand, eliminates tax-free distributions from charitable remainder trusts due to manipulation of the timing of the distributions. A particular distribution could run afoul of either of these rules, or both rules.

In response to this comment, and to further clarify the different functions of the two rules, some minor changes have been made to the proposed regulation to eliminate references to timing and to clarify the application of the deemed sale rule. In addition, in order to make it less likely that a non-abusive trust would violate the payment rule, two new exceptions have been added to §§ 1.664–2(a)(1)(i)(a) and 1.664–3(a)(1)(i)(g). These new exceptions provide that a distribution of cash made within a reasonable period of time after the close of the year may be characterized as corpus under section 664(b)(4) to the extent it was attributable to (i) a contribution of cash to the trust with respect to which a deduction was allowable under section 170, 2055, 2106, or 2522, or (ii) a return of basis in any asset contributed to the trust with respect to which a deduction was allowable under section 170, 2055, 2106, or 2522, and sold by the trust during the year for which the annuity or unitrust amount was due.

One commentator asserted that the proposed regulations should not apply to charitable remainder trusts established prior to the date the proposed regulations were published in the **Federal Register**. This commentator compared the effective date of the proposed regulations to the effective date of the 1997 Act's trust provisions. Each of the changes made by the 1997 Act applies to transfers made to trusts after the date specified in the 1997 Act, while the regulations apply to distributions made by trusts after October 18, 1999.

The Treasury Department and the IRS do not believe this assertion has merit. These effective dates are not comparable because the 1997 Act and these regulations apply to different aspects of charitable remainder trusts. The 1997 Act changed the requirements a trust must meet to qualify as a charitable remainder trust. Whether a trust qualifies as a charitable remainder trust is determined at the time property is transferred to the trust. As a result, it was appropriate to set the effective dates for the 1997 Act with respect to the time that transfers were made to a trust. The regulations, on the other hand, change the character of a distribution from a charitable remainder trust. The character of a distribution from a charitable remainder trust is not determined until after the distribution is made. Accordingly, the regulations can be applied, without being retroactive, to distributions made after the date the proposed regulations were filed with the **Federal Register**. Section 7805(b)(1). Furthermore, the Treasury Department and the IRS would have had the authority under section 7805(b)(3) to write regulations that take effect retroactively to prevent abuse. The abuse targeted by these regulations is well documented in Notice 94–78 (1994–2 C.B. 555), the legislative history to the 1997 Act, the changes to the charitable remainder trust regulations that were finalized in 1998 (TD 8791, 1999–5 I.R.B. 7), and Notice 2000–15 (2000–12 I.R.B. 826).

Finally, the preamble to the proposed regulations requested comments on two specific issues: (1) Whether there are situations where the application of the proposed regulation would be inappropriate, and (2) whether an approach that more directly related the distributed funds to the asset that is the subject of the borrowing or forward sale would be more appropriate. No comments were received on either of these issues.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the understanding of the Treasury Department and the IRS that the number of charitable remainder trusts engaging in transactions affected by these regulations is not substantial, and none are small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. chapter 6). Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the preceding notice of proposed rulemaking was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal authors of these regulations are Mary Beth Collins and Catherine Moore, Office of Chief Counsel (Passthroughs and Special Industries). However, other personnel

from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.643(a)–8 also issued under 26 U.S.C. 643(a)(7). * * *

Par. 2. Section 1.643(a)–8 is added to read as follows:

§ 1.643(a)–8 Certain distributions by charitable remainder trusts.

(a) *Purpose and scope.* This section is intended to prevent the avoidance of the purposes of the charitable remainder trust rules regarding the characterizations of distributions from those trusts in the hands of the recipients and should be interpreted in a manner consistent with this purpose. This section applies to all charitable remainder trusts described in section 664 and the beneficiaries of such trusts.

(b) *Deemed sale by trust.* (1) For purposes of section 664(b), a charitable remainder trust shall be treated as having sold, in the year in which a distribution of an annuity or unitrust amount is made from the trust, a pro rata portion of the trust assets to the extent that the distribution of the annuity or unitrust amount would (but for the application of this paragraph (b)) be characterized in the hands of the recipient as being from the category described in section 664(b)(4) and exceeds the amount of the previously undistributed

(i) Cash contributed to the trust (with respect to which a deduction was allowable under section 170, 2055, 2106, or 2522); plus

(ii) Basis in any contributed property (with respect to which a deduction was allowable under section 170, 2055, 2106, or 2522) that was sold by the trust.

(2) Any transaction that has the purpose or effect of circumventing the rules in this paragraph (b) shall be disregarded.

(3) For purposes of paragraph (b)(1) of this section, trust assets do not include cash or assets purchased with the proceeds of a trust borrowing, forward sale, or similar transaction.

(4) Proper adjustment shall be made to any gain or loss subsequently realized for gain or loss taken into account under paragraph (b)(1) of this section.

(c) *Examples.* The following examples illustrate the rules of paragraph (b) of this section:

Example 1. Deemed sale by trust. Donor contributes stock having a fair market value of $2 million to a charitable remainder unitrust with a unitrust amount of 50 percent of the net fair market value of the trust assets and a two-year term. The stock has a total adjusted basis of $400,000. In Year 1, the trust receives dividend income of $20,000. As of the valuation date, the trust's assets have a net fair market value of $2,020,000 ($2 million in stock, plus $20,000 in cash). To obtain additional cash to pay the unitrust amount to the noncharitable beneficiary, the trustee borrows $990,000 against the value of the stock. The trust then distributes $1,010,000 to the beneficiary before the end of Year 1. Under section 664(b)(1), $20,000 of the distribution is characterized in the hands of the beneficiary as dividend income. The rest of the distribution, $990,000, is attributable to an amount received by the trust that did not represent either cash contributed to the trust or a return of basis in any contributed asset sold by the trust during Year 1. Under paragraph (b)(3) of this section, the stock is a trust asset because it was not purchased with the proceeds of the borrowing. Therefore, in Year 1, under paragraph (b)(1) of this section, the trust is treated as having sold $990,000 of stock and as having realized $792,000 of capital gain (the trust's basis in the shares deemed sold is $198,000). Thus, in the hands of the beneficiary, $792,000 of the distribution is characterized as capital gain under section 664(b)(2) and $198,000 is characterized as a tax-free return of corpus under section 664(b)(4). No part of the $990,000 loan is treated as acquisition indebtedness under section 514(c) because the entire loan has been recharacterized as a deemed sale.

Example 2. Adjustment to trust's basis in assets deemed sold. The facts are the same as in *Example 1.* During Year 2, the trust sells the stock for $2,100,000. The trustee uses a portion of the proceeds of the sale to repay the outstanding loan, plus accrued interest. Under paragraph (b)(4) of this section, the trust's adjusted basis in the stock is $1,192,000 ($400,000 plus the $792,000 of gain recognized in Year 1). Therefore, the trust recognizes capital gain (as described in section 664(b)(2)) in Year 2 of $908,000.

Example 3. Distribution of cash contributions. Upon the death of D, the proceeds of a life insurance policy on D's life are payable to T, a charitable remainder annuity trust. The terms of the trust provide that, for a period of three years commencing upon D's death, the trust shall pay an annuity amount equal to $x annually to A, the child of D. After the expiration of such three-year period, the remainder interest in the trust is to be transferred to charity Z. In Year 1, the trust receives payment of the life insurance proceeds and pays the appropriate pro rata portion of the $x annuity to A from the insurance proceeds. During Year 1, the trust has no income. Because the entire distribution is attributable to a cash contribution (the insurance proceeds) to the trust for which a charitable deduction was allowable under section 2055 with respect to the present value of the remainder interest passing to charity, the trust will not be treated as selling a pro rata portion of the trust assets under paragraph (b)(1) of this section. Thus, the distribution is characterized in A's hands as a tax-free return of corpus under section 664(b)(4).

(d) *Effective date.* This section is applicable to distributions made by a charitable remainder trust after October 18, 1999.

Par. 3. Section 1.664–1 is amended as follows:

1. Paragraph (d)(1)(iii) is redesignated as paragraph (d)(1)(iv).

2. New paragraph (d)(1)(iii) is added.

The addition reads as follows:

§ 1.664–1 Charitable remainder trusts.

* * * * *

(d) * * *

(1) * * *

(iii) *Application of section 643(a)(7).* For application of the anti-abuse rule of section 643(a)(7) to distributions from charitable remainder trusts, see § 1.643(a)–8.

* * * * *

Par. 4. § 1.664–2 is amended as follows:

1. Paragraphs (a)(1)(i)(*a*)(*1*) and (a)(1)(i)(*a*)(*2*) are revised.

2. Paragraph (a)(1)(i)(*a*)(*3*) is added.

3. Paragraph (a)(1)(i)(*e*) is amended by adding a sentence at the end.

The revision and additions read as follows:

§ 1.664–2 Charitable remainder annuity trust.

(a) * * *

(1) * * * (i) * * *

(*a*) * * *

(*1*) The trust pays the annuity amount by distributing property (other than cash) that it owned at the close of the taxable year to pay the annuity amount, and the trustee elects to treat any income generated by the distribution as occurring on the last day of the taxable year in which the annuity amount is due;

(*2*) The trust pays the annuity amount by distributing cash that was contributed to the trust (with respect to which a deduction was allowable under section 170, 2055, 2106, or 2522); or

(*3*) The trust pays the annuity amount by distributing cash received as a return of basis in any asset that was contributed to the trust (with respect to which a deduction was allowable under section 170, 2055, 2106, or 2522), and

that is sold by the trust during the year for which the annuity amount is due.

* * * * *

(*e*) * * * However, paragraphs (a)(1)(i)(*a*)(*2*) and (*3*) of this section apply only to distributions made on or after January 5, 2001.

* * * * *

Par. 5. § 1.664–3 is amended as follows:

1. Paragraphs (a)(1)(i)(*g*)(*1*) and (a)(1)(i)(*g*)(*2*) are revised.

2. Paragraph (a)(1)(i)(*g*)(*3*) is added.

3. Paragraph (a)(1)(i)(*l*) is amended by adding a sentence at the end.

The revision and additions read as follows.

* * * * *

(*g*) * * *

(*1*) The trust pays the unitrust amount by distributing property (other than cash) that it owned at the close of the taxable year, and the trustee elects to treat any income generated by the distribution as occurring on the last day of the taxable year in which the unitrust amount is due;

(*2*) The trust pays the unitrust amount by distributing cash that was contributed to the trust (with respect to which a deduction was allowable under section 170, 2055, 2106, or 2522); or

(*3*) The trust pays the unitrust amount by distributing cash received as a return of basis in any asset that was contributed to the trust (with respect to which a deduction was allowable under section 170, 2055, 2106, or 2522), and that is sold by the trust during the year for which the unitrust amount is due.

* * * * *

(*l*) * * * Paragraphs (a)(1)(i)(*g*)(*2*) and (*3*) apply only to distributions made on or after January 5, 2001.

* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: December 13, 2000.

Jonathan Talisman,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 01–248 Filed 1–4–01; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8917]

RIN 1545–AW75

Section 467 Rental Agreements Involving Payments of $2,000,000 or Less

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations concerning section 467 rental agreements. The regulations provide amendments to the regulations under section 467, including the removal of the exception to constant rental accrual for rental agreements involving payments of $2,000,000 or less. The regulations affect taxpayers that are parties to a section 467 rental agreement.

DATES: *Effective Date:* These regulations are effective January 5, 2001.

Dates of Applicability: For dates of applicability of these regulations, see Effective Dates under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Forest Boone, (202) 622–4960 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR Part 1 under section 467 of the Internal Revenue Code (Code). Section 467 was added to the Code by section 92(a) of the Tax Reform Act of 1984 (Public Law 98–369; 98 Stat. 609).

On May 18, 1999, a notice of proposed rulemaking (REG–103694–99, 1999–24, I.R.B. 49) under section 467 was published in the **Federal Register** (64 FR 26924). The notice proposed to amend the section 467 regulations relating to constant rental accrual by treating section 467 rental agreements involving payments of $2,000,000 or less in the same manner as agreements involving payments of more than $2,000,000. Although comments and requests for a public hearing were solicited, no comments were received and no public hearing was requested or held. Accordingly, the amendment to the constant rental accrual rules called for by the proposed regulations is adopted without revision.

In addition, the IRS and Treasury Department have identified three provisions in the section 467 regulations (TD 8820), published on May 18, 1999, at 64 FR 26845, that require clarification. Accordingly, these final regulations also provide clarifying amendments to the section 467 regulations.

Explanation of Provisions

A. Removal of the $2,000,000 Constant Rental Accrual Exception

Section 467 includes an anti-abuse rule applicable to certain section 467 rental agreements. Under this rule, a constant rental amount must be taken into account by a lessor and lessee for each rental period during the lease term. The constant rental amount is the amount that, if paid at the end of each rental period, would result in a present value equal to the present value of all amounts payable under the agreement.

Constant rental accrual applies only with respect to leasebacks and long-term agreements that provide for increasing or decreasing rent and only if the Commissioner determines that the agreement is disqualified because tax avoidance is a principal purpose for providing increasing or decreasing rent. In addition, however, the regulations provide that a rental agreement will not be disqualified and, consequently, will not be subject to constant rental accrual unless it requires more than $2,000,000 in rental payments and other consideration.

These final regulations remove the $2,000,000 exception from constant rental accrual for section 467 rental agreements entered into on or after July 19, 1999. Consequently, for section 467 rental agreements entered into on or after July 19, 1999, the Commissioner may determine that the agreement is a disqualified leaseback or long-term agreement subject to constant rental accrual, even if the agreement requires $2,000,000 or less in rental payments and other consideration.

B. Definition of Lease Term

Section 1.467–1(h)(6) defines lease term to mean ''the period during which the lessee has use of the property subject to the rental agreement, including any option to renew or extend the term of the agreement *other than an option, exercisable by the lessee, as to which it is reasonably expected, as of the agreement date, that the option will not be exercised.*'' [Emphasis added]. By contrast, the proposed regulations preceding the section 467 final regulations stated that an option period, whether exercisable by the lessor or lessee, is included in the lease term only if it is expected, as of the agreement date, that the option will be exercised. The purpose of the broader rule in the

final regulations was to include all lessor option periods in the lease term. The IRS and Treasury Department recognize, however, that the broader rule has caused some uncertainty as to whether a change in the treatment of lessee options, particularly those exercisable at fair market value rental, was also intended. These regulations clarify that a change in the treatment of lessee options was not intended. They provide, in language similar to that of the proposed section 467 regulations, that lessee options are to be included in the lease term only if it is expected, as of the agreement date, that the option will be exercised. For this purpose, a lessee is generally expected to exercise an option if, for example, as of the agreement date the rent for the option period is less than the expected fair market value rental for such period. It should be noted, however, that factors other than the relationship between rent and expected fair market value rental for the option period may be relevant in determining whether it is expected that a lessee option will be exercised. Thus, even in the case of a lessee option exercisable at fair market value rental, it may, on account of such other relevant factors, be expected that the option will be exercised.

C. When an Amount Is Considered Payable

Section 1.467–1(j)(2)(ii) provides that, for purposes of determining present value and yield under the regulations, an amount is payable on the last day for timely payment (the last day for timely payment rule). The last day for timely payment is the last day such amount may be paid without incurring interest, computed at an arm's-length rate, a substantial penalty, or other substantial detriment (such as giving the lessor the right to terminate the agreement, bring an action to enforce payment, or exercise other similar remedies under the terms of the agreement or applicable law).

The IRS and Treasury Department believe that the last day for timely payment rule, applicable to the computation of present value and yield, should also apply to other cases in which the date on which an amount is payable is relevant for purposes of section 467. Accordingly, the section 467 regulations have been amended to provide that, for purposes of applying all of the section 467 rules, not just those dealing with present value and yield, an amount is payable on the last day for timely payment.

D. Adequate Interest for Agreements With Both Deferred and Prepaid Rent

Under the section 467 regulations, the fixed rent for each rental period is the proportional rental amount if the section 467 rental agreement is not a disqualified leaseback or long-term agreement and if the agreement does not provide adequate interest on fixed rent. The regulations set forth rules for determining whether an agreement has adequate interest on fixed rent. These regulations clarify how these rules apply in the case of agreements with both deferred and prepaid rent.

E. Effective Dates

The removal of the exception from constant rental accrual for rental agreements involving payments of $2,000,000 or less is applicable for section 467 rental agreements entered into on or after July 19, 1999. The other amendments in these regulations are applicable to rental agreements entered into after March 6, 2001. However, taxpayers may choose to apply these amendments to rental agreements entered into on or before March 6, 2001.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of the regulations is Forest Boone, Office of Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the IRS and Treasury Department participated in the development of the regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par 2. Section 1.467–0 is amended by adding an entry for § 1.467–2(b)(3) to read as follows:

§ 1.467–0 Table of contents.

* * * * *

§ 1.467–2 Rent accrual for section 467 rental agreements without adequate interest.

* * * * *

(b) * * *

(3) Agreements with both deferred and prepaid rent.

* * * * *

Par 3. Section 1.467–1 is amended by revising paragraphs (h)(6) and (j)(2)(ii) to read as follows:

§ 1.467–1 Treatment of lessors and lessees generally.

* * * * *

(h) * * *

(6) *Lease term* means the period during which the lessee has use of the property subject to the rental agreement, including any option of the lessor to renew or extend the term of the agreement. An option of the lessee to renew or extend the term of the agreement is included in the lease term only if it is expected, as of the agreement date, that the option will be exercised. For this purpose, a lessee is generally expected to exercise an option if, for example, as of the agreement date the rent for the option period is less than the expected fair market value rental for such period. The lessor's or lessee's determination that an option period is either included in or excluded from the lease term is not binding on the Commissioner. If the lessee (or a related person) agrees that one or both of them will or could be obligated to make payments in the nature of rent (within the meaning of § 1.168(i)–2(b)(2)) for a period when another lessee (the substitute lessee) or the lessor will have use of the property subject to the rental agreement, the Commissioner may, in appropriate cases, treat the period when the substitute lessee or lessor will have use of the property as part of the lease term. See § 1.467–7(f) for special rules applicable to the lessee, substitute lessee, and lessor. This paragraph (h)(6) applies to section 467 rental agreements entered into after March 6, 2001. However, taxpayers may choose to apply this paragraph (h)(6) to any rental agreement that is described in § 1.467–

9(a) and is entered into on or before March 6, 2001.

* * * * *

(j) * * *

(2) * * *

(ii) *Time amount is payable.* For purposes of this section and §§ 1.467–2 through 1.467–9, an amount is payable on the last day for timely payment (that is, the last day such amount may be paid without incurring interest, computed at an arm's-length rate, a substantial penalty, or other substantial detriment (such as giving the lessor the right to terminate the agreement, bring an action to enforce payment, or exercise other similar remedies under the terms of the agreement or applicable law)). This paragraph (j)(2)(ii) applies to section 467 rental agreements entered into after March 6, 2001. However, taxpayers may choose to apply this paragraph (j)(2)(ii) to any rental agreement that is described in § 1.467–9(a) and is entered into on or before March 6, 2001.

* * * * *

Par 4. In § 1.467–2, paragraph (b)(3) is added to read as follows:

§ 1.467–2 Rent accrual for section 467 rental agreements without adequate interest.

* * * * *

(b) * * *

(3) *Agreements with both deferred and prepaid rent.* If an agreement has both deferred and prepaid rent, the agreement provides adequate interest under paragraph (b)(1) of this section if the conditions set forth in paragraph (b)(1)(ii)(A) through (D) of this section are met for both the prepaid and the deferred rent. For purposes of this paragraph (b)(3), an agreement will be considered to meet the condition set forth in paragraph (b)(1)(ii)(A) of this section if the agreement provides a single fixed rate of interest on the deferred rent and a single fixed rate of interest on the prepaid rent, even if those rates are not the same. This paragraph (b)(3) applies to section 467 rental agreements entered into after March 6, 2001. However, taxpayers may choose to apply this paragraph (b)(3) to any rental agreement that is described in § 1.467–9(a) and is entered into on or before March 6, 2001.

* * * * *

Par 5. In § 1.467–3, paragraph (b)(1)(iii) is revised to read as follows:

§ 1.467–3 Disqualified leasebacks and long-term agreements.

* * * * *

(b) * * * (1) * * *

(iii) For section 467 rental agreements entered into before July 19, 1999, the amount determined with respect to the rental agreement under § 1.467–1(c)(4) (relating to the exception for rental agreements involving total payments of $250,000 or less) exceeds $2,000,000.

* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: December 12, 2000.

Jonathan Talisman,

Acting Assistant Secretary of the Treasury.

[FR Doc. 01–253 Filed 1–4–01; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 20, and 25

[TD 8923]

RIN 1545–AX74

Lifetime Charitable Lead Trusts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the definitions of a guaranteed annuity interest and a unitrust interest for purposes of the income, gift, and estate tax charitable deductions. The regulations affect taxpayers who make transfers to charitable lead trusts. The regulations restrict the permissible terms for charitable lead trusts and are necessary to ensure that the amount the taxpayer claims as a charitable deduction reasonably correlates to the amount ultimately passing to the charitable organization.

DATES: *Effective Dates:* These regulations are effective January 5, 2001.

Applicability Dates: For dates of applicability of these regulations, see §§ 1.170A–6(e), 20.2055–2(e)(3)(iii), and 25.2522(c)–3(e).

FOR FURTHER INFORMATION CONTACT: Scott S. Landes at (202) 622–3090.

SUPPLEMENTARY INFORMATION:

Background

On April 5, 2000, the IRS published in the **Federal Register** (65 FR 17835) a notice of proposed rulemaking (REG–100291–00) relating to the permissible terms for charitable guaranteed annuity interests and unitrust interests. This document adopts final regulations with respect to the notice of proposed rulemaking. Written comments were received with respect to the proposed regulations, but no public hearing was requested or held. A summary of the principal comments received is provided below.

In general, in order to qualify as a guaranteed annuity interest or unitrust interest for purposes of the income, estate, and gift tax charitable deductions under sections 170(c), 2055(e)(2), and 2522(c)(2), respectively, the permissible term for the charitable lead interest must be either a specified term of years, or the life or lives of individuals living at the date of the transfer. The proposed regulations limit the individuals who may be used as measuring lives to the donor, the donor's spouse, and a lineal ancestor of all the remainder beneficiaries. This proposed limitation is intended to eliminate abusive schemes utilizing seriously ill individuals, who are unrelated to the grantor or the remainder beneficiaries, as measuring lives for charitable lead trusts.

Commentators argued that by limiting the class of individuals who can be used as measuring lives in a charitable lead trust, the regulations preclude the use of these trusts in certain nonabusive situations. In response to these comments, several changes were made to the final regulations to provide a greater degree of flexibility for selecting a measuring life.

The final regulations expand the class of permissible measuring lives to include an individual who, with respect to all noncharitable remainder beneficiaries, is either a lineal ancestor or the spouse of a lineal ancestor of those beneficiaries. Thus, remainder beneficiaries can include step-children and step-grandchildren of the individual who is the measuring life, and charitable organizations (described in section 170, 2055, or 2522).

The final regulations also provide that a trust will satisfy the requirement that all noncharitable remainder beneficiaries are lineal descendants of the individual who is the measuring life, or that individual's spouse, if there is less than a 15% probability that individuals who are not lineal descendants will receive any trust corpus. This probability must be computed at the date of transfer to the trust taking into consideration the interests of all individuals living at that time. This change will afford drafters the flexibility to provide for alternative remainder beneficiaries in the event the primary remainder beneficiary and his or her descendants predecease the individual who is the measuring life for the term of the charitable interest.

The application of the probability test may be illustrated by assuming a grantor establishes a charitable lead annuity trust (CLAT) that provides for the

annuity to be paid to a charity for the life of A who is age 75 on the date the CLAT is created. On A's death, the corpus is to pass to A's only child, B, age 50 on the date the CLAT is created. If B predeceases A, the corpus is to pass to B's issue then living and if B has no living issue at that time, then to A's heirs at law (which class could include A's siblings, uncles, aunts, nieces and nephews). B has no living children on the date the CLAT is created. Based on the current applicable Life Table contained in § 20.2031–7 of the Estate Tax Regulations (Life Table 90CM), the probability that B will predecease A, and the trust will pass to individuals who are not lineal descendants of A is 10.462%, taking into account the interests of remainder beneficiaries living at the time the trust was created. Since the probability that any trust corpus will pass to beneficiaries who are not lineal descendants of A is less than 15%, the CLAT will satisfy the requirement that all noncharitable remainder beneficiaries are lineal descendants of A or A's spouse.

Several commentators identified hypothetical situations where an individual who is either unrelated to the remainder beneficiaries, or a remote family member, could be used as a measuring life to achieve an estate planning objective. The commentators suggested three alternative standards that would expand the class of permissible measuring lives. None of these suggestions has been adopted.

First, one commentator suggested that the regulations allow a charitable lead trust to use as a measuring life an ancestor of any remainder beneficiary rather than an ancestor of all remainder beneficiaries. Under the suggested standard, the charitable lead trust could provide a nominal remainder interest for descendants of the measuring life, with the balance passing to the grantor's family members. Thus, the standard would do little to prevent the abuse the regulations are intended to address.

Second, one commentator suggested that the regulations provide that an individual is a permissible measuring life if all remainder beneficiaries are natural objects of the individual's bounty. However, the determination of whether a person is the natural object of one's bounty requires an inquiry into facts that may be difficult to ascertain or verify. Such a subjective standard would create uncertainty and would be difficult to administer.

Third, one commentator suggested that if the charitable interest is payable for the life of an individual, then the trust must require that, in the event the individual fails to survive to a normal life expectancy, a guaranteed lump sum will be paid to charity (determined actuarially), that will make up for the shortfall in the charitable annuity. A provision requiring such a payment in the event of the premature death of the measuring life would be complex and inconsistent with the valuation rules of section 7520. In addition, this requirement would in substance convert a life interest to a term of years interest and in some cases allow that term interest to be commuted. Thus, such a requirement may conflict with other rules prohibiting commutation or prepayment of the charitable lead interest.

In summary, the Treasury Department and the IRS acknowledge that there may be situations in which the grantor, for a valid estate planning objective, may desire to use an individual as a measuring life who does not satisfy the criteria in the regulations (for example, where a remainder beneficiary is dependent on a nonfamily member for support and the trust corpus is intended to provide that support after the death of the nonfamily member). However, the Treasury Department and the IRS believe that in these situations the grantor's objectives can be satisfied through the use of other permissible estate planning techniques. In situations where a charitable lead trust is utilized, the Treasury Department and the IRS believe that the final regulations allow adequate flexibility for achieving legitimate estate planning objectives while providing reasonable safeguards to preclude abusive arrangements.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Scott S. Landes, Office of the Chief Counsel, IRS. Other personnel from the IRS and the Treasury Department participated in their development.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1, 20, and 25 are amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.170A–6 also issued under 26 U.S.C. 170(f)(4); 26 U.S.C. 642(c)(5). * * *

Par. 2. Section 1.170A–6 is amended as follows:

1. Paragraph (c)(2)(i)(A) is amended as follows:

a. In the first sentence, the comma is removed.

b. In the second sentence, the language ''of years'' is added after the word ''term'', the language ''an individual or individuals'' is removed, and ''certain individuals'' is added in its place.

c. The third sentence is removed, and six new sentences are added in its place.

d. In the penultimate sentence, the language ''of years'' is added after the word ''term'', the language ''an individual'' is removed, and ''the donor'' is added in its place.

2. Paragraph (c)(2)(ii)(A) is amended as follows:

a. In the fifth sentence, the language ''of years'' is added after the word ''term'', ''an individual or individuals'' is removed, and ''certain individuals'' is added in its place.

b. The last sentence is removed, and six new sentences are added in its place.

3. Paragraph (e) is amended by adding four sentences to the end of the paragraph.

4. The authority citation at the end of the section is removed.

The additions read as follows:

§ 1.170A–6 Charitable contributions in trust.

* * * * *

(c) * * *

(2) * * *

(i) * * * (A) * * * Only one or more of the following individuals may be used as measuring lives: the donor, the donor's spouse, and an individual who, with respect to all remainder beneficiaries (other than charitable organizations described in section 170, 2055, or 2522), is either a lineal ancestor or the spouse of a lineal ancestor of those beneficiaries. A trust will satisfy the requirement that all noncharitable remainder beneficiaries are lineal descendants of the individual who is the measuring life, or that individual's

spouse, if there is less than a 15% probability that individuals who are not lineal descendants will receive any trust corpus. This probability must be computed, based on the current applicable Life Table contained in § 20.2031–7, at the time property is transferred to the trust taking into account the interests of all primary and contingent remainder beneficiaries who are living at that time. An interest payable for a specified term of years can qualify as a guaranteed annuity interest even if the governing instrument contains a savings clause intended to ensure compliance with a rule against perpetuities. The savings clause must utilize a period for vesting of 21 years after the deaths of measuring lives who are selected to maximize, rather than limit, the term of the trust. The rule in this paragraph that a charitable interest may be payable for the life or lives of only certain specified individuals does not apply in the case of a charitable guaranteed annuity interest payable under a charitable remainder trust described in section 664. * * *

* * * * *

(ii) * * * (A) * * * Only one or more of the following individuals may be used as measuring lives: the donor, the donor's spouse, and an individual who, with respect to all remainder beneficiaries (other than charitable organizations described in section 170, 2055, or 2522), is either a lineal ancestor or the spouse of a lineal ancestor of those beneficiaries. A trust will satisfy the requirement that all noncharitable remainder beneficiaries are lineal descendants of the individual who is the measuring life, or that individual's spouse, if there is less than a 15% probability that individuals who are not lineal descendants will receive any trust corpus. This probability must be computed, based on the current applicable Life Table contained in § 20.2031–7, at the time property is transferred to the trust taking into account the interests of all primary and contingent remainder beneficiaries who are living at that time. An interest payable for a specified term of years can qualify as a unitrust interest even if the governing instrument contains a savings clause intended to ensure compliance with a rule against perpetuities. The savings clause must utilize a period for vesting of 21 years after the deaths of measuring lives who are selected to maximize, rather than limit, the term of the trust. The rule in this paragraph that a charitable interest may be payable for the life or lives of only certain specified individuals does not apply in the case of a charitable unitrust interest payable under a charitable remainder trust described in section 664.

* * * * *

(e) *Effective date.* * * * In addition, the rule in paragraphs (c)(2)(i)(A) and (ii)(A) of this section that guaranteed annuity interests and unitrust interests, respectively, may be payable for a specified term of years or for the life or lives of only certain individuals applies to transfers made on or after April 4, 2000. If a transfer is made to a trust on or after April 4, 2000 that uses an individual other than one permitted in paragraphs (c)(2)(i)(A) and (ii)(A) of this section, the trust may be reformed to satisfy this rule. As an alternative to reformation, rescission may be available for a transfer made on or before March 6, 2001. See § 25.2522(c)–3(e) of this chapter for the requirements concerning reformation or possible rescission of these interests.

PART 20—ESTATE TAX; ESTATES OF DECEDENTS DYING AFTER AUGUST 16, 1954

Par. 3. The authority citation for part 20 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 4. Section 20.2055–2 is amended as follows:

1. Paragraph (e)(2)(vi) (*a*) is amended as follows:

a. In the third sentence, the language ''of years'' is added after the word ''term'', the language ''an individual or individuals'' is removed, and ''certain individuals'' is added in its place.

b. The fourth sentence is removed, and six new sentences are added in its place.

c. In the penultimate sentence, the language ''of years'' is added after the word ''term'', the language ''an individual'' is removed, and ''the decedent's spouse'' is added in its place.

2. Paragraph (e)(2)(vii)(*a*) is amended as follows:

a. In the sixth sentence, the language ''of years'' is added after the word ''term'', the language ''of an individual or individuals'' is removed, and ''of certain individuals'' is added in its place.

b. The last sentence is removed, and six new sentences are added in its place.

3. Paragraph (e)(3) is amended as follows:

a. The period at the end of paragraph (e)(3)(ii)(*c*) is removed, a comma is added and the word ''and'' is added after the comma.

b. A new paragraph (e)(3)(iii) is added.

The additions read as follows:

§ 20.2055–2 Transfers not exclusively for charitable purposes.

* * * * *

(e) * * *

(2) * * *

(vi) * * * (*a*) * * * Only one or more of the following individuals may be used as measuring lives: the decedent's spouse, and an individual who, with respect to all remainder beneficiaries (other than charitable organizations described in section 170, 2055, or 2522), is either a lineal ancestor or the spouse of a lineal ancestor of those beneficiaries. A trust will satisfy the requirement that all noncharitable remainder beneficiaries are lineal descendants of the individual who is the measuring life, or that individual's spouse, if there is less than a 15% probability that individuals who are not lineal descendants will receive any trust corpus. This probability must be computed, based on the current applicable Life Table contained in § 20.2031–7, as of the date of the decedent's death taking into account the interests of all primary and contingent remainder beneficiaries who are living at that time. An interest payable for a specified term of years can qualify as a guaranteed annuity interest even if the governing instrument contains a savings clause intended to ensure compliance with a rule against perpetuities. The savings clause must utilize a period for vesting of 21 years after the deaths of measuring lives who are selected to maximize, rather than limit, the term of the trust. The rule in this paragraph that a charitable interest may be payable for the life or lives of only certain specified individuals does not apply in the case of a charitable guaranteed annuity interest payable under a charitable remainder trust described in section 664. * * *

* * * * *

(vii) * * * (*a*) * * * Only one or more of the following individuals may be used as measuring lives: the decedent's spouse, and an individual who, with respect to all remainder beneficiaries (other than charitable organizations described in section 170, 2055, or 2522), is either a lineal ancestor or the spouse of a lineal ancestor of those beneficiaries. A trust will satisfy the requirement that all noncharitable remainder beneficiaries are lineal descendants of the individual who is the measuring life, or that individual's spouse, if there is less than a 15% probability that individuals who are not lineal descendants will receive any trust corpus. This probability must be computed, based on the current applicable Life Table contained in

§ 20.2031–7, as of the date of the decedent's death taking into account the interests of all primary and contingent remainder beneficiaries who are living at that time. An interest payable for a specified term of years can qualify as a unitrust interest even if the governing instrument contains a savings clause intended to ensure compliance with a rule against perpetuities. The savings clause must utilize a period for vesting of 21 years after the deaths of measuring lives who are selected to maximize, rather than limit, the term of the trust. The rule in this paragraph that a charitable interest may be payable for the life or lives of only certain specified individuals does not apply in the case of a charitable unitrust interest payable under a charitable remainder trust described in section 664.

* * * * *

(3) * * *

(iii) The rule in paragraphs (e)(2)(vi)(*a*) and (vii)(*a*) of this section that guaranteed annuity interests or unitrust interests, respectively, may be payable for a specified term of years or for the life or lives of only certain individuals is generally effective in the case of transfers pursuant to wills and revocable trusts where the decedent dies on or after April 4, 2000. Two exceptions from the application of this rule in paragraphs (e)(2)(vi)(*a*) and (vii)(*a*) of this section are provided in the case of transfers pursuant to a will or revocable trust executed on or before April 4, 2000. One exception is for a decedent who dies on or before July 5, 2001, without having republished the will (or amended the trust) by codicil or otherwise. The other exception is for a decedent who was on April 4, 2000, under a mental disability to change the disposition of the decedent's property, and either does not regain competence to dispose of such property before the date of death, or dies prior to the later of: 90 days after the date on which the decedent first regains competence, or July 5, 2001, without having republished the will (or amended the trust) by codicil or otherwise. If a guaranteed annuity interest or unitrust interest created pursuant to a will or revocable trust where the decedent dies on or after April 4, 2000, uses an individual other than one permitted in paragraphs (e)(2)(vi)(*a*) and (vii)(*a*) of this section, and the interest does not qualify for this transitional relief, the interest may be reformed into a lead interest payable for a specified term of years. The term of years is determined by taking the factor for valuing the annuity or unitrust interest for the named individual measuring life and identifying the term of years (rounded up to the next whole year) that corresponds to the equivalent term of years factor for an annuity or unitrust interest. For example, in the case of an annuity interest payable for the life of an individual age 40 at the time of the transfer, assuming an interest rate of 7.4% under section 7520, the annuity factor from column 1 of Table S(7.4), contained in IRS Publication 1457, Book Aleph, for the life of an individual age 40 is 12.0587 (Publication 1457 is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402). Based on Table B(7.4), contained in Publication 1457, Book Aleph, the factor 12.0587 corresponds to a term of years between 31 and 32 years. Accordingly, the annuity interest must be reformed into an interest payable for a term of 32 years. A judicial reformation must be commenced prior to the later of July 5, 2001, or the date prescribed by section 2055(e)(3)(C)(iii). Any judicial reformation must be completed within a reasonable time after it is commenced. A non-judicial reformation is permitted if effective under state law, provided it is completed by the date on which a judicial reformation must be commenced. In the alternative, if a court, in a proceeding that is commenced on or before July 5, 2001, declares any transfer made pursuant to a will or revocable trust where the decedent dies on or after April 4, 2000, and on or before March 6, 2001, null and void ab initio, the Internal Revenue Service will treat such transfers in a manner similar to that described in section 2055(e)(3)(J).

* * * * *

PART 25—GIFT TAX; GIFTS MADE AFTER DECEMBER 31, 1954

Par. 5. The authority citation for part 25 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 6. Section 25.2522(c)–3 is amended as follows:

1. Paragraph (c)(2)(vi)(*a*) is amended as follows:

a. In the third sentence, the language ''of years'' is added after the word ''term'', the language ''a named individual or individuals'' is removed, and ''certain individuals'' is added in its place.

b. The fourth sentence is removed, and six new sentences are added in its place.

c. In the sentence beginning ''For example, the amount'', the language ''of years'' is added after the word ''term'', the language ''an individual'' is removed, and ''the donor'' is added in its place.

2. Paragraph (c)(2)(vii)(*a*) is amended as follows:

a. In the sixth sentence, the language ''of years'' is added after the word ''term'', the language ''an individual or individuals'' is removed, and ''certain individuals'' is added in its place.

b. The last sentence is removed, and six new sentences are added in its place.

3. Paragraph (e) is amended by adding nine new sentences to the end of the paragraph.

The additions read as follows:

§ 25.2522(c)–3 Transfers not exclusively for charitable, etc., purposes in the case of gifts made after July 31, 1969.

* * * * *

(c) * * *

(2) * * *

(vi) * * * (*a*) * * * Only one or more of the following individuals may be used as measuring lives: the donor, the donor's spouse, and an individual who, with respect to all remainder beneficiaries (other than charitable organizations described in section 170, 2055, or 2522), is either a lineal ancestor or the spouse of a lineal ancestor of those beneficiaries. A trust will satisfy the requirement that all noncharitable remainder beneficiaries are lineal descendants of the individual who is the measuring life, or that individual's spouse, if there is less than a 15% probability that individuals who are not lineal descendants will receive any trust corpus. This probability must be computed, based on the current applicable Life Table contained in § 20.2031–7, at the time property is transferred to the trust taking into account the interests of all primary and contingent remainder beneficiaries who are living at that time. An interest payable for a specified term of years can qualify as a guaranteed annuity interest even if the governing instrument contains a savings clause intended to ensure compliance with a rule against perpetuities. The savings clause must utilize a period for vesting of 21 years after the deaths of measuring lives who are selected to maximize, rather than limit, the term of the trust. The rule in this paragraph that a charitable interest may be payable for the life or lives of only certain specified individuals does not apply in the case of a charitable guaranteed annuity interest payable under a charitable remainder trust described in section 664. * * *

* * * * *

(vii) * * * (*a*) * * * Only one or more of the following individuals may be used as measuring lives: the donor, the donor's spouse, and an individual

who, with respect to all remainder beneficiaries (other than charitable organizations described in section 170, 2055, or 2522), is either a lineal ancestor or the spouse of a lineal ancestor of those beneficiaries. A trust will satisfy the requirement that all noncharitable remainder beneficiaries are lineal descendants of the individual who is the measuring life, or that individual's spouse, if there is less than a 15% probability that individuals who are not lineal descendants will receive any trust corpus. This probability must be computed, based on the current applicable Life Table contained in § 20.2031–7, at the time property is transferred to the trust taking into account the interests of all primary and contingent remainder beneficiaries who are living at that time. An interest payable for a specified term of years can qualify as a unitrust interest even if the governing instrument contains a savings clause intended to ensure compliance with a rule against perpetuities. The savings clause must utilize a period for vesting of 21 years after the deaths of measuring lives who are selected to maximize, rather than limit, the term of the trust. The rule in this paragraph that a charitable interest may be payable for the life or lives of only certain specified individuals does not apply in the case of a charitable unitrust interest payable under a charitable remainder trust described in section 664.

* * * * *

(e) *Effective date.* * * * In addition, the rule in paragraphs (c)(2)(vi)(*a*) and (vii)(*a*) of this section that guaranteed annuity interests or unitrust interests, respectively, may be payable for a specified term of years or for the life or lives of only certain individuals applies to transfers made on or after April 4, 2000. If a transfer is made on or after April 4, 2000, that uses an individual other than one permitted in paragraphs (c)(2)(vi)(*a*) and (vii)(*a*) of this section, the interest may be reformed into a lead interest payable for a specified term of years. The term of years is determined by taking the factor for valuing the annuity or unitrust interest for the named individual measuring life and identifying the term of years (rounded up to the next whole year) that corresponds to the equivalent term of years factor for an annuity or unitrust interest. For example, in the case of an annuity interest payable for the life of an individual age 40 at the time of the transfer, assuming an interest rate of 7.4% under section 7520, the annuity factor from column 1 of Table S(7.4), contained in IRS Publication 1457, Book Aleph, for the life of an individual age 40 is 12.0587 (Publication 1457 is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402). Based on Table B(7.4), contained in Publication 1457, Book Aleph, the factor 12.0587 corresponds to a term of years between 31 and 32 years. Accordingly, the annuity interest must be reformed into an interest payable for a term of 32 years. A judicial reformation must be commenced prior to October 15th of the year following the year in which the transfer is made and must be completed within a reasonable time after it is commenced. A non-judicial reformation is permitted if effective under state law, provided it is completed by the date on which a judicial reformation must be commenced. In the alternative, if a court, in a proceeding that is commenced on or before July 5, 2001, declares any transfer, made on or after April 4, 2000, and on or before March 6, 2001, null and void ab initio, the Internal Revenue Service will treat such transfers in a manner similar to that described in section 2055(e)(3)(J).

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: December 20, 2000.

Jonathan Talisman,

Acting Assistant Secretary of the Treasury.

[FR Doc. 01–254 Filed 1–4–01; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–00–124]

RIN 2115–AE46

Special Local Regulations; Hillsborough Bay, Tampa, FL

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily modifying the special local regulation for the annual Gasparilla Marine Parade in Tampa, Florida. The event sponsor changed the event time and date for this year from the first Saturday in February, 2001, to January 27, 2001. These regulations are needed to provide for the safety of life on navigable waters during the event.

DATES: This rule is effective from 8 a.m. to 6 p.m. EST on January 27, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD 07–00–124 and are available for inspection or copying at Commander, Coast Guard Group St. Petersburg, 600 8th Avenue, S.E., St. Petersburg, FL 33701, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Chief Quartermaster Stephen Aykroyd Coast Guard Group St. Petersburg, Florida at (727) 824–7554.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM would have been impracticable, as there was not sufficient time remaining after the changes to the event time and date were finalized.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

Ye Mystic Krewe of Gasparilla is sponsoring the annual Parade of Pirates in Hillsborough Bay on January 27, 2001. There will be approximately four hundred (400) spectator craft. A special local regulation exists at 33 C.F.R. 100.734 for this event which is usually held on the first Saturday in February. However, the sponsor changed the date for this year. These regulations are intended to promote safe navigation on the waters of Tampa Bay by controlling the traffic entering, exiting, and traveling within the regulated area.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. The Office of Management and Budget has exempted it from review under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. Entry into the regulated area is prohibited for only approximately 10 hours.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612) we considered whether this rule will have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their field, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in the northern part of Hillsborough Bay on January 27, 2001 from 8 a.m. to 6 p.m.

This special local regulation will not have a significant economic impact on a substantial number of small entities because the regulation will only be in effect for 10 hours in a limited area.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that the rule does not have implications for federalism under that order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environmental Assessment

The Coast Guard has considered the environmental impact of this action and has determined under Figure 2–1, paragraph 34(h) of Commandant Instruction M16475.1C, that this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR Part 100 as follows:

PART 100—MARINE EVENTS

1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233, 49 CFR 1.46 and 33 CFR 100.35.

2. Temporarily suspend § 100.734 and add temporary § 100.35T–00–124 to read as follows:

§ 100.35T–00–124 Annual Gasparilla Marine Parade, Hillsborough Bay, Tampa, FL.

(a) *Regulated Area.* A regulated area is established consisting of all waters of Hillsborough Bay and its tributaries north of a line drawn along latitude 27–51.30N. The regulated area includes the following in their entirety: Hillsborough Cut ''D'' Channel, Sparkman Channel, Ybor Channel, Seddon Channel and the Hillsborough River south of the John F. Kennedy Bridge. Coordinates Reference Datum: NAD 1983.

(b) *Special local regulations.* (1) Entry into the regulated area is prohibited to all commercial marine traffic from 8 a.m. to 6 p.m. EST on January 27, 2001.

(2) The regulated area is an idle speed, ''no wake'' zone.

(3) All vessels within the regulated area shall stay clear of and give way to all vessels in parade formation in the Gasparilla Marine Parade.

(4) When within the marked channels of the parade route, vessels participating in the Gasparilla Marine Parade may not exceed the minimum speed necessary to maintain steerage.

(5) Personnel water craft and vessels without mechanical propulsion are prohibited from the parade route.

(6) Northbound vessels in excess of 80 feet in length without mooring arrangements made prior to January 27, 2001, are prohibited from entering Seddon Channel unless the vessel is officially entered in the Gasparilla Marine Parade. All northbound vessels in excess of 80 feet without prior mooring arrangements not officially entered in the Gasparilla Marine Parade, must use the alternate route through Sparkman Channel.

(c) *Date.* This rule is effective from 8 a.m. to 6 p.m. EST on January 27, 2001.

Dated: December 27, 2000.

G.W. Sutton,

Captain, U.S. Coast Guard, Commander, Seventh Coast Guard District, Acting.

[FR Doc. 01–345 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD07–00–134]

Drawbridge Operation Regulations; Anna Maria Bridge, Across the Gulf Intracoastal Waterway, Mile 89.2, Bradenton, FL

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Anna Maria bridge across the Gulf Intracoastal Waterway, mile 89.2, Bradenton, Florida. This temporary deviation allows the drawbridge owner or operator to open only a single leaf between 8 am and 4 pm, from January 1, 2001 through February 28, 2001. This temporary deviation is required to allow the bridge owner to safely complete repairs of the bridge.

DATES: This deviation is effective from January 1, 2001 to February 28, 2001.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Chief, Operations Section, Seventh Coast Guard District, Bridge Section at (305) 415–6743.

SUPPLEMENTARY INFORMATION: The Anna Maria bridge across the Gulf Intracoastal Waterway at Brandenton, is a double leaf bridge with a vertical clearance of 25 feet above mean high water (MHW) measured at the fenders in the closed position with a horizontal clearance of 90 feet. On December 13, 2000, Florida Department of Transportation, the drawbridge owner, requested a

deviation from the current operating regulation in 33 CFR 117.5 which requires drawbridge to open promptly and fully when a request to open is given. This temporary deviation was requested to allow necessary repairs to the drawbridge in a critical time sensitive manner.

The District Commander has granted a temporary deviation from the operating requirements listed in 33 CFR 117.35 for the purpose of repair completion of the drawbridge. Under this deviation, the Anna Maria Bridge need only open one leaf from 8 am until 4 pm, from January 1, 2001 until February 28, 2001. Single leaf closures will occur intermittently during this time period.

Dated: December 21, 2000.

Greg E. Shapley,

Chief, Bridge Administration, Seventh Coast Guard District.

[FR Doc. 01–346 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–15–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NV033–FON; FRL–6929–1]

Finding of Failure To Submit a Required State Implementation Plan for Particulate Matter, Nevada-Clark County

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to find that Nevada failed to make particulate matter (PM–10) nonattainment area state implementation plan (SIP) submittals required for the Las Vegas Valley Planning Area under the Clean Air Act (CAA or Act). The Las Vegas Planning Area was originally classified as a moderate PM–10 nonattainment area, but was later reclassified as serious. Under certain provisions of the Act, states are required to submit SIPs providing for, among other things, reasonable further progress and attainment of the PM–10 national ambient air quality standards (NAAQS) in areas classified as moderate and serious. The State of Nevada submitted several plans intended to meet these requirements. On June 14, 2000, EPA proposed to disapprove these SIP submittals. On December 5, 2000, prior to any final action by EPA, the State of Nevada withdrew the submittals. As a result of the State's withdrawal of the moderate and serious area SIP submittals, EPA is today finding that Nevada failed to make the PM–10 nonattainment area SIP submittals required for the Las Vegas Valley Planning Area under the Act.

This action triggers the 18-month time clock for mandatory application of sanctions and 2-year time clock for a federal implementation plan (FIP) under the Act. This action is consistent with the CAA mechanism for assuring SIP submissions.

EFFECTIVE DATE: This action is effective as of December 20, 2000.

FOR FURTHER INFORMATION CONTACT: Kenneth Israels, U.S. Environmental Protection Agency, Region 9, Air Division (AIR–2), 75 Hawthorne Street, San Francisco, CA 94105–3901, Telephone: (415) 744–1194.

SUPPLEMENTARY INFORMATION:

I. Background

A. CAA Planning Requirements

In 1990, Congress amended the Clean Air Act to address, among other things, continued nonattainment of the PM–10 NAAQS.[1] Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q (1991). On the date of enactment of the Amendments, PM–10 areas meeting the qualifications of section 107(d)(4)(B) of the amended Act were designated nonattainment by operation of law. These areas included all former Group I areas identified in 52 FR 29383 (August 7, 1987) and clarified in 55 FR 45799 (October 31, 1980), and any other areas violating the PM–10 NAAQS prior to January 1, 1989. The Las Vegas Valley Planning Area was identified in the August 7, 1987, **Federal Register** (52 FR 29384). A **Federal Register** action announcing all areas designated nonattainment for PM–10 at enactment of the 1990 amendments was published on March 15, 1991 (56 FR 11101). The boundaries of the Las Vegas Valley nonattainment area (Hydrographic Area 212) are codified at 40 CFR 81.329.

Once an area is designated nonattainment, section 188 of the amended Act outlines the process for classification of the area and establishes the area's attainment date. In accordance with section 188(a), at the time of designation, all PM–10 nonattainment areas, including Las Vegas Valley, were initially classified as moderate by operation of law. Section 188(b)(1) of the Act further provides that moderate areas can subsequently be reclassified as serious before the applicable moderate area attainment date if at any time EPA determines that the area cannot ''practicably'' attain the PM–10 NAAQS by that date.

Air monitoring of the Las Vegas Valley during the past 18 years has measured some of the highest PM–10 pollution in the United States. Nevada submitted a moderate area PM–10 plan for the Las Vegas Valley on December 6, 1991. Based on this submittal, EPA determined on January 8, 1993, that the Las Vegas Valley could not practicably attain both the annual and 24-hour standards by the applicable attainment deadline for moderate areas (December 31, 1994, per section 188(c)(1) of the Act), and reclassified the Las Vegas Valley as serious (58 FR 3334). In accordance with section 189(b)(2) of the Act, SIP revisions for the Las Vegas Valley addressing the requirements for serious PM–10 nonattainment areas in section 189(b) and (c) of the Act were required to be submitted by August 8, 1994 and February 8, 1997.

The moderate and serious area requirements, as they currently pertain to the Las Vegas Valley nonattainment area, include: [2]

(a) A demonstration (including air quality modeling) that the plan will provide for attainment as expeditiously as practicable but no later than December 31, 2001, or an alternative demonstration that attainment by that date would be impracticable and that the plan provides for attainment by the most expeditious alternative date

[1] EPA revised the NAAQS for PM–10 on July 1, 1987 (52 FR 24672), replacing standards for total suspended particulates with new standards applying only to particulate matter up to 10 microns in diameter (PM–10). At that time, EPA established two PM–10 standards. The annual PM–10 standard is attained when the expected annual arithmetic average of the 24-hour samples for a period of one year does not exceed 50 micrograms per cubic meter (ug/m^3). The 24-hour PM–10 standard of 150 ug/m^3 is attained if samples taken for 24-hour periods have no more than one expected exceedance per year, averaged over 3 years. See 40 CFR 50.6 and 40 CFR part 50, appendix K.

On July 18, 1997, EPA reaffirmed the annual PM–10 standard, and slightly revised the 24-hour PM–10 standard (62 FR 38651). The revised 24-hour PM–10 standard is attained if the 99th percentile of the distribution of the 24-hour results over 3 years does not exceed 150 ug/m^3 at each monitor within an area.

This finding applies to the outstanding obligation of the State to submit plans for the Las Vegas Valley Planning Area addressing the 24-hour and annual PM–10 standards, as originally promulgated.

Breathing particulate matter can cause significant health effects, including an increase in respiratory illness and premature death.

[2] EPA has concluded that certain moderate area PM–10 requirements continue to apply after an area has been reclassified to serious. For a more detailed discussion of the planning requirements applicable to the Las Vegas Valley and the relationship between the moderate area and serious area requirements after the reclassification of the area to serious, see 65 FR 37324–37326 (June 14, 2000).

practicable (CAA section 189(b)(1)(A)(i) and (ii));

(b) Quantitative milestones which are to be achieved every 3 years and which demonstrate reasonable further progress toward attainment by December 31, 2001 (CAA section 189(c)).

(c) Provisions to assure that reasonably available control (RACM), including reasonably available control technology (RACT), measures shall be implemented as soon as practicable (CAA section 189(a)(1)(C)); and

(d) Provisions to assure that the best available control measures (BACM), including best available control technology (BACT) shall be implemented no later than four years after the reclassification of the area to a serious nonattainment area (CAA section 189(b)(1)(B).

B. Nevada's PM–10 SIP Submittals for the Las Vegas Valley

The State of Nevada submitted the following plans that were prepared by the Clark County Department of Comprehensive Planning (CCDCP) to address the CAA's moderate and serious area requirements for the Las Vegas Valley Planning Area:

1. The PM–10 moderate area nonattainment plan titled ''PM–10 Air Quality Implementation Plan, Las Vegas Valley, Clark County, Nevada'' (1991 Moderate Plan), submitted to EPA on December 6, 1991;

2. An ''Addendum to the 'Moderate Area' PM–10 State Implementation Plan for the Las Vegas Valley'' (1995 RACM Addendum), submitted to EPA on February 15, 1995;

3. A BACM analysis plan titled ''Providing for the Evaluation, Adoption and Implementation of Best Available Control Measures and Best Available Control Technology to Improve PM–10 Air Quality'' (1994 BACM Plan), submitted to EPA on December, 1994; and

4. The PM–10 serious area nonattainment plan for the Las Vegas Valley nonattainment area titled ''Particulate Matter (PM–10) Attainment Demonstration Plan'' (1997 Serious Plan), submitted to EPA on August 25, 1997.

The term ''Moderate Area SIP'' in this action refers collectively to the 1991 Moderate Plan and the 1995 RACM Addendum; ''Serious Area SIP'' refers collectively to the 1994 BACM Plan and the 1997 Serious Plan. These submittals became complete by operation of law.[3]

[3] EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

C. EPA Actions Relating to Nevada's PM–10 SIP Submittals for the Las Vegas Valley

On June 14, 2000, EPA proposed to disapprove both the Moderate Area SIP and the Serious Area SIP for the Las Vegas Valley Planning Area. See 65 FR 37324. Two comments supporting our proposed action were received.

On December 5, 2000, prior to EPA's taking final action on its proposed disapproval, the State of Nevada withdrew the Moderate Area SIP and the Serious Area SIP. See letter dated December 5, 2000 from Allen Biaggi, Administrator of the Division of Environmental Protection, Nevada Department of Conservation and Natural Resources to Felicia Marcus, Regional Administrator, EPA Region 9.

The CAA establishes specific consequences if EPA finds that a State has failed to meet certain requirements of the CAA. Of particular relevance here is CAA section 179(a)(1), the mandatory sanctions provision. Section 179(a) sets forth four findings that form the basis for application of a sanction. The first finding, that a State has failed to submit a plan required under the CAA, is the finding relevant to this rulemaking because withdrawal of a plan is tantamount to failing to submit it.

If Nevada has not made the required complete submittal (in this case resubmittal) within 18 months of the effective date of today's rulemaking, pursuant to CAA section 179(a) and 40 CFR 52.31, the offset sanction identified in CAA section 179(b) will be applied in the affected area. If the State has still not made a complete submission 6 months after the offset sanction is imposed, then the highway funding sanction will apply in the affected area, in accordance with 40 CFR 52.31.[4] The 18-month clock will stop and the sanctions will not take effect if, within 18 months after the date of the finding, EPA finds that the State has made a complete submittal of a plan addressing the applicable moderate area and the serious area PM–10 requirements for the Las Vegas Valley.

In addition, CAA section 110(c)(1) provides that EPA must promulgate a federal implementation plan (FIP) no later than 2 years after a finding under section 179(a) unless EPA takes final action to approve the submittal within 2 years of EPA's finding.

EPA encourages the responsible parties to work together on a solution in a broad, open public process which can result in the avoidance of the sanctions and FIP.

D. Recent Developments in Nevada

Since November, 1998, we have been working with CCDCP to develop an approvable SIP that would replace those we proposed to disapprove in June 2000. On October 30, 2000, EPA received a 60-day notice of intent to sue under section 304(a)(2) of the CAA from the Sierra Club alleging that we had failed to take final action on the 1997 Serious Plan by the CAA deadline. While in the midst of finalizing our disapproval action, the State of Nevada withdrew both the Moderate Area SIP and Serious Area SIP from EPA consideration. As noted above, the withdrawal means that EPA cannot finalize the proposed disapproval action and the Agency is compelled to find that the State of Nevada has failed to make the required SIP submissions for the Las Vegas Valley PM–10 nonattainment area.[5]

EPA is hopeful that in addition to withdrawing these plans, CCDCP intends to consult more broadly and openly with stakeholders concerned with the planning process; EPA urges them to do so. EPA is encouraged by recent efforts by CCDCP to develop an approvable PM–10 SIP that would replace the ones which have been withdrawn.

EPA believes that some of the work found in the most recent CCDCP draft plan[6] will contribute towards attaining the 24-hour and annual PM–10 standards. For instance, they have:

- Adopted several new fugitive dust rules for significant sources, as well as some of the most advanced and stringent Best Management Practices for construction sites among PM–10 nonattainment areas,
- Conducted studies to identify vacant land in the Las Vegas Valley and they are engaging in public outreach efforts to vacant land owners regarding compliance with new requirements,

[4] In a 1994 rulemaking, EPA established the Agency's selection of the sequence of these two sanctions: the offset sanction under section 179(b)(2) shall apply at 18 months, followed 6 months later by the highway sanction under section 179(b)(1) of the Act. EPA does not choose to deviate from this presumptive sequence in this instance. For more details on the timing and implementation of the sanctions, see 59 FR 39832 (August 4, 1994), promulgating 40 CFR 52.31, ''Selection of sequence of mandatory sanctions for findings made pusuant to section 179 of the Clean Air Act.''

[5] EPA notes that the sanctions for failing to submit these plans are identical to those which would have been imposed had we finalized our disapproval action.

[6] This plan, which was informally submitted to EPA on September 11, 2000, is entitled ''PM–10 State Implementation Plan for Clark County—September 2000 Draft.'' Some of this work is being currently implemented by the Clark County Health District.

• Committed to hire additional staff to conduct inspections of fugitive dust sources to ensure rule compliance, and

• Funded near-term research on standards/test methods for fugitive dust sources.

However, EPA notes that while we are encouraged by the work of CCDCP in developing an approvable PM–10 replacement SIP, we have also identified significant concerns with the draft plan that we have reviewed so far. Specifically, EPA is concerned about:[7]

(1) The underlying data (including whether or not all emission sources are included) which ultimately must result in an accurate emissions inventory,

(2) How the use of the locally-implemented paved road offset program may affect attainment and conformity,

(3) The plan's treatment of mobile source emissions growth,

(4) The plan's incomplete or inadequate process for determining appropriate controls for the area and measurement standards/techniques for certain sources (RACM/BACM and the most stringent measures analysis under CAA section 188(e)),

(5) The plan's inaccurate determination that BACT application is unnecessary at sources which are clearly subject to such federal requirements,

(6) An overall strategy to attain which inappropriately assumes future construction occurring on all vacant land within the nonattainment area,[8]

(7) Failure to integrate the conformity budget into the plan so that the budget and the plan can be shown to be working together towards attainment, and

(8) Failure to address significant elements necessary to justify an extension of time to achieve attainment of PM–10 standards.

We are hopeful that by CCDCP working with the local agencies and business, environmental, and other stakeholders, our concerns will be addressed with the submittal of an approvable PM–10 SIP for the Las Vegas Valley area. Further, it is our understanding that CCDCP intends to adopt a plan which addresses our concerns on the following schedule:

• January 5, 2001—CCDCP will send a second draft of their draft plan to EPA for comment,

• March 20, 2001—CCDCP presents the draft plan to their Board and opens the public comment period on the plan,

• April 20, 2001—CCDCP will close the public comment period,

• June 2001—CCDCP's Board will approve the plan, and

• Late June 2001—State of Nevada will submit the plan to EPA for action.

II. Final Action

A. Rule

EPA is today making a finding that the State of Nevada failed to submit SIP revisions addressing the CAA's moderate and serious area PM–10 requirements to attain the 24-hour and annual PM–10 NAAQS for the Las Vegas Valley PM–10 nonattainment area.

B. Effective Date Under the Administrative Procedures Act

Today's action will be effective on December 20, 2000. Under the Administrative Procedures Act (APA), 5 U.S.C. 553(d)(3), agency rulemaking may take effect before 30 days after the date of publication in the **Federal Register** if an agency has good cause to mandate an earlier effective date. Today's action concerns a SIP submission that is already overdue and the State has been aware of applicable provisions of the CAA relating to overdue SIPs. In addition, today's action simply starts a ''clock'' that will not result in sanctions for 18 months, and that the State may ''turn off'' through the submission of a complete SIP submittal. These reasons support an effective date prior to 30 days after the date of publication.

C. Notice-and-Comment Under the Administrative Procedures Act

This final agency action is not subject to the notice-and-comment requirements of the APA, 5 U.S.C. 533(b). EPA believes that because of the limited time provided to make findings of failure to submit regarding SIP submissions, Congress did not intend such findings to be subject to notice-and-comment rulemaking. However, to the extent such findings are subject to notice-and-comment rulemaking, EPA invokes the good cause exception pursuant to the APA, 5 U.S.C. 553(d)(3). Notice and comment are unnecessary because no EPA judgment is involved in making a nonsubstantive finding of failure to submit SIPs required by the CAA. Furthermore, providing notice and comment would be impracticable because of the limited time provided under the statute for making such determinations. Finally, notice and comment would be contrary to the public interest because it would divert Agency resources from the critical substantive review of submitted SIPs. See 58 FR 51270, 51272, note 17 (October 1, 1993); 59 FR 39832, 39853 (August 4, 1994).

III. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled ''Regulatory Planning and Review.''

B. Executive Order 13045

Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

C. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal

[7] This list is not exhaustive. See letter from Kenneth F. Bigos, EPA to John Schlegel, CCDCP, dated November 15, 2000 for additional details.

[8] EPA notes that this is consistent with concerns that the Sierra Club raised both in its comment letter on the June 14, 2000 proposed disapproval action and in its October 30, 2000 notice of intent to sue EPA.

governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

D. Executive Order 13132

Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612, Federalism and 12875, Enhancing the Intergovernmental Partnership. Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This final rule will not have a significant impact on a substantial number of small entities because findings of failure to submit required SIP revisions do not by themselves create any new requirements. Therefore, I certify that this action will not have a significant economic impact on a substantial number of small entities.

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that today's action does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. The CAA provision discussed in this notice requires states to submit SIPs. This notice merely provides a finding that Nevada has not met that requirement. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

EPA believes that VCS are inapplicable to today's action because it does not require the public to perform activities conducive to the use of VCS.

H. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. However, section 808 provides that any rule for which the issuing agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule) that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest, shall take effect at such time as the agency promulgating the rule determines. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefore, and established an effective date of December 20, 2000. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 6, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Particulate matter, Intergovernmental relations, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: December 20, 2000.

Amy Zimpfer,

Acting Regional Administrator, Region IX.

[FR Doc. 01–221 Filed 1–4–01; 8:45 am]

BILLING CODE 6560–50–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

40 CFR Part 1610

Representation of Witnesses in Agency Investigations

AGENCY: Chemical Safety and Hazard Investigation Board.

ACTION: Final rule.

SUMMARY: This document sets forth the Chemical Safety and Hazard Investigation Board's regulations for the representation of witnesses in agency investigations. It covers representation by attorneys of witnesses in depositions or other situations where testimony is compelled and representation by attorneys or non-attorney representatives of witnesses who are appearing voluntarily for interviews.

DATES: Effective January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Raymond C. Porfiri, (202) 261–7600.

SUPPLEMENTARY INFORMATION: The Chemical Safety and Hazard Investigation Board (''CSB'' or ''Board'') is mandated by law to ''Investigate (or cause to be investigated), determine and report to the public in writing the facts, conditions, and circumstances and the cause or probable cause of any accidental release [within its jurisdiction] resulting in a fatality, serious injury or substantial property damages.'' 42 U.S.C. 7412(r)(6)(C)(i). The Board has developed practices and procedures for conducting investigations under this provision and has determined that its procedures and policies concerning witness representation should be published in the **Federal Register** and codified in the Code of Federal Regulations for wider public dissemination. These rules codify the law concerning witness representation as set forth in the Administrative Procedure Act, 5 U.S.C. 555(b). Because they concern a matter of agency organization, procedure, or practice, notice-and-comment procedures are not required and are not provided here. 5 U.S.C. 553(b)(B).

It should be noted that CSB administrative investigations are purely investigatory and that the CSB lacks the authority to determine anyone's civil or criminal liability, or make any other determination depriving a person of life, liberty or property. Its enabling statute prohibits any part of the ''conclusions, findings, or recommendations of the Board'' from being admitted as evidence or used in any other way in civil suits arising from incidents investigated by the CSB. 42 U.S.C. 7212(r)(6)(G). Witnesses in CSB proceedings are not targets of the investigation, do not have their legal rights at issue, and as such are not entitled to the sort of due process protections that attend agency adjudications. *See Hannah* v. *Larche,* 363 U.S. 420 (1960).

The Administrative Procedure Act does, however, provide that witnesses who are ''compelled to appear in person'' before the agency may be ''accompanied, represented, and advised by counsel, or if permitted by the agency by other qualified representative.'' 5 U.S.C. 555(b). The Board's rule codifies this provision and provides that witnesses compelled to appear (normally for a deposition) may be accompanied, represented, and advised by an attorney. The Board, in its discretion, has determined not to provide for non-attorney representation in such situations.

The CSB practice, which is being codified in this final rule, provides reasonable ''ground rules'' for attorney participation in witness depositions. It is modeled, in part, on the regulation of the Federal Trade Commission, 16 CFR 2.9(b).

The CSB also is providing guidance to witnesses who appear voluntarily for interviews. In such circumstances, the agency's Investigator-in-Charge, in consultation with the General Counsel, may permit the witness to be accompanied by an attorney or a non-attorney representative, but there is no right to such representation. The Administrative Procedure Act does not mandate a right to representation for non-compulsory appearances. 5 U.S.C. 555(b).

Regulatory Flexibility Act

The Board, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Dated: December 22, 2000.

Christopher W. Warner,

General Counsel.

List of Subjects in 40 CFR Part 1610,

Administrative practice and procedure, Investigations.

For the reasons set forth in the preamble, the Chemical Safety and Hazard Investigation Board adds a new 40 CFR part 1610 as follows:

PART 1610—ADMINISTRATIVE INVESTIGATIONS

Sec.

Authority: 42 U.S.C. 7412(r)(6)(C)(i), 7412(r)(6)(L), 7412(r)(6)(N)

§ 1610.1 Representation of witnesses in investigations.

(a) *Witnesses who are compelled to appear.* Witnesses who are compelled to appear for a deposition (i.e., by subpoena) are entitled to be accompanied, represented, and advised by an attorney as follows:

(1) Counsel for a witness may advise the witness with respect to any question asked where it is claimed that the testimony or other evidence sought from a witness is outside the scope of the investigation, or that the witness is privileged to refuse to answer a question or to produce other evidence. For these allowable objections, the witness or counsel for the witness may object on the record to the question or requirement and may state briefly and precisely the ground therefor. If the witness refuses to answer a question, then counsel may briefly state on the record that counsel has advised the witness not to answer the question and the legal grounds for such refusal. The witness and his or her counsel shall not otherwise object to or refuse to answer any question, and they shall not otherwise interrupt the oral examination.

(2) Any objections made will be treated as continuing objections and preserved throughout the further course of the deposition without the necessity for repeating them as to any similar line of inquiry. Cumulative objections are unnecessary. Repetition of the grounds for any objection will not be allowed.

(3) Counsel for a witness may not, for any purpose or to any extent not allowed by paragraphs (a)(1) and (2) of this section, interrupt the examination of the witness by making any objections or statements on the record.

(4) Following completion of the examination of a witness, counsel for the witness may on the record request the person conducting the deposition to permit the witness to clarify any of his or her answers. The grant or denial of such request shall be within the sole discretion of the person conducting the deposition.

(5) The person conducting the deposition shall take all necessary action to regulate the course of the deposition, to avoid delay, and to prevent or restrain disorderly, dilatory, obstructionist, or contumacious conduct, or contemptuous language. Such person shall, for reasons stated on the record, immediately report to the Board any instances where an attorney has allegedly refused to comply with his or her directions, or has allegedly engaged in disorderly, dilatory, obstructionist, or contumacious conduct, or contemptuous language in the course of the deposition. The Board may thereupon take such further action, if any, as the circumstances warrant, including exclusion of that attorney from further participation in the particular investigation.

(b) *Voluntary interviews.* Witnesses appearing voluntarily do not have a right to have an attorney present during questioning. The Investigator-in-Charge (IIC), in consultation with the General Counsel, may permit a witness to be accompanied by an attorney or non-attorney representative. If so accompanied, the role of the attorney or non-attorney representative is limited to raising objections to questions that are outside the scope of the investigation and to advising the witness with respect to any legal privilege such as, for example, under the Fifth Amendment to the U. S. Constitution. Attorney and non-attorney representatives may not represent more than one witness in each investigation in this fashion, absent the consent of the IIC and the General Counsel.

[FR Doc. 01–288 Filed 1–4–01; 8:45 am]

BILLING CODE 6350–01–U

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Part 1247

[STB Ex Parte No. 583]

Modification of the Class I Reporting Regulations

AGENCY: Surface Transportation Board.

ACTION: Final rules.

SUMMARY: New regulations, requiring all Class I railroads to report the number of railroad cars loaded and terminated annually are adopted. The new reporting requirement will ensure the continued availability of important data—heretofore only voluntarily reported to, and supplied to the Surface Transportation Board (Board) by, the Association of American Railroads (AAR)—needed by the Board for application of the Uniform Railroad Costing System (URCS), its railroad cost accounting system.

EFFECTIVE DATE: January 1, 2001.

FOR FURTHER INFORMATION CONTACT: Paul A. Aguiar, (202) 565–1527 or H. Jeff Warren, (202) 565–1533. [Assistance for the hearing impaired is available through the Federal Information Relay Service 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: In a Notice of Proposed Rulemaking (NPR) served July 18, 2000, comments were solicited on modifying Chapter X of the Code of Federal Regulations Title 49, Part 1247 to require Class I railroads to submit a new report—Annual Report of Cars Loaded and Cars Terminated (Form STB–54). This new report would require Class I railroads to report the number of cars loaded and terminated during each calendar year. Currently, the AAR collects such data quarterly and aggregates the information on a yearly basis in its annual reports (AAR Form CS–54–1) for each railroad.

Historically, we have relied on AAR Form CS–54–1 to obtain certain inputs for URCS. However, to ensure the continued availability of these data, we proposed that Class I railroads file an abbreviated version of AAR Form CS–54–1 with the Board. We proposed to require the reporting of only that data used as inputs for URCS—sections A and B of AAR Form CS–54–1.

Comments on the NPR were filed by the Western Coal Traffic League, United Transportation Union-Illinois Legislative Board (UTU–IL), and the U.S. Department of Agriculture. All three parties fully support the proposal. In addition, UTU–IL suggests that we: (1) Require the carriers to file quarterly, as well as annual, information; (2) make Form STB–54 data available for inspection in our public reference room rather than in the Office of Economics, Environmental Analysis, and Administration (OEEAA); and (3) adopt a definition of ''dependent short line'' railroads and require Class I railroads to list their dependent short lines.[1]

[1] Traffic loaded and terminated on dependent short line railroads is to be reported by Class I railroads as if it was loaded or terminated by the Class I carrier.

We will adopt the proposed reporting requirement supported by all commenters. We decline, however, to adopt UTU–IL's additional proposals. Regarding the suggestion to have railroads file quarterly data, it would be inappropriate to adopt the UTU–IL proposal without first affording railroads the opportunity to comment. More importantly, we see no reason to burden the railroads with filing quarterly data that we would not use. While UTU–IL contends that the filing of quarterly data will assure ''the integrity of the process,'' it has not explained why that is so, and we fail to see how filing such data would provide any benefit.

In addition, we see no need to maintain a second set of Form STB–54 data in our public reference room. UTU–IL has not shown that housing the data in OEEAA will place any unreasonable burden on the public or limit access to the information. Indeed, all other cost and traffic data reported by the railroads are available to the public only in OEEAA and we have received no reports of dissatisfaction with this arrangement. Because the data is used on a regular basis by OEEAA staff, it is administratively most practical to house the data where it is used and UTU–IL has provided no compelling reason to maintain a duplicate set of data in the public reference room.

Finally, under our proposal, we expect the railroads to apply the term ''dependent short line'' in the same manner as it has been applied in prior years to compile AAR Form CS–54–1. This will ensure comparability of data from year-to-year. We see no need, and UTU–IL has suggested none, to have railroads provide a list of their dependent short lines. Because it is our longstanding policy not to burden the industry by requiring the filing of unneeded information, we reject this proposal.

The regulations set forth below are adopted and will be codified at 49 CFR 1247. Copies of Form STB–54 and its instructions will be available on the Board's web site under forms (*http://www.stb.dot.gov/infoex1.htm#forms*). Alternatively, copies can be requested by writing or calling the contact persons listed above.

This action will not significantly affect either the quality of the human environment or energy conservation.

Because only large railroads will be affected by the new reporting requirement, we conclude that our action will not have a significant economic impact on a substantial number of small entities within the

meaning of the Regulatory Flexibility Act.

List of Subjects in 49 CFR Part 1247

Freight, Railroads, Reporting and recordkeeping requirements.

Decided: December 29, 2000.

By the Board, Chairman Morgan, Vice Chairman Burkes, Commissioner Clyburn.

Vernon A. Williams,

Secretary.

For the reasons set forth above, Title 49, Part 1247 Report of Cars Loaded and Cars Terminated is added to Chapter X of the Code of Federal Regulations to read as follows:

PART 1247—REPORT OF CARS LOADED AND CARS TERMINATED

Authority: 49 U.S.C. 721, 10707, 11144, 11145.

§ 1247.1 Annual Report of Cars Loaded and Cars Terminated.

Beginning with the reporting period commencing January 1, 2001, and annually thereafter, each Class I railroad shall file Form STB–54, Annual Report of Cars Loaded and Cars Terminated, together with the accompanying certification, with the Office of Economics, Environmental Analysis, and Administration (OEEAA), Surface Transportation Board, Washington, DC 20243, within 90 days after the end of the reporting year. Blank forms and instructions are available on the Board's web site (*http://www.stb.dot.gov/infoex1.htm#forms*) or can be obtained by contacting OEEAA.

[FR Doc. 01–328 Filed 1–4–01; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AG08

Migratory Bird Hunting; Late Seasons and Bag and Possession Limits for Certain Migratory Game Birds

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; correction.

SUMMARY: The U.S. Fish and Wildlife Service (hereinafter Service or we) published a document in the September 28, 2000, **Federal Register** prescribing the hunting seasons, hours, areas, and daily bag and possession limits for general waterfowl seasons and those early seasons for which States previously deferred selection. This document corrects errors in the season dates and other pertinent information for the States of Florida, Idaho, and Tennessee.

DATES: This rule was effective on September 29, 2000.

FOR FURTHER INFORMATION CONTACT: Jon Andrew, Chief, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, (703) 358–1714.

SUPPLEMENTARY INFORMATION: In the September 28, 2000, **Federal Register** (65 FR 58314), we published a final rule prescribing hunting seasons, hours, areas, and daily bag and possession limits for general waterfowl seasons, certain other migratory bird seasons, and those early seasons for which States previously deferred selection. The rule contained errors in the introductory language for several sections and entries for Florida, Idaho, and Tennessee, which are discussed briefly below and corrected by this notice.

We received public comment on the proposed rules for the seasons and limits established by the September 28 final rule. We addressed these comments in the August 23, 2000, (65 FR 51496) and September 27, 2000, (65 FR 58152) **Federal Register**. The corrections are typographical in nature and involve no change in substance in the contents of the prior proposed and final rules.

§ 20.104 [Corrected]

1. On page 58316 under the heading *Seasons, limits, and shooting hours for rails, woodcock, and common snipe,* the second introductory paragraph is corrected to read ''Shooting and hawking hours are one-half hour before sunrise until sunset, except as otherwise restricted by State regulations. Area descriptions were published in the August 23, 2000, (65 FR 51496) and September 27, 2000, (65 FR 58152) **Federal Register**.''

2. On page 58316 under the heading *Pacific Flyway,* the heading ''Idaho'' is inserted above the heading *Nevada;* under the heading *Idaho,* the subheading ''Zone 1'' is inserted; across from the subheading *Zone 1,* the season dates of ''Oct. 7–Jan. 19'' are inserted in the column for *common snipe;* under the subheading *Zone 1,* the subheading ''Zone 2 & 3'' is inserted; across from the subheading *Zone 2 & 3,* the season dates of ''Oct. 7–Oct. 18 & Oct. 21–Jan. 21'' are inserted in the column for *common snipe.*

§ 20.105 [Corrected]

1. On page 58317 under the heading *Seasons, limits, and shooting hours for waterfowl, coots, and gallinules,* the second introductory paragraph is corrected to read ''Shooting and hawking hours are one-half hour before sunrise until sunset, except as otherwise restricted by State regulations. Area descriptions were published in the August 23, 2000, (65 FR 51496) and September 27, 2000, (65 FR 58152) **Federal Register**.''

2. On page 58325 under the heading *Tennessee,* subheading *Geese,* subheading *Light Geese,* the possession limit of ''30'' is corrected to read ''none.''

3. On page 58330 under the heading *Florida,* the season dates ''Jan. 27 &'' are corrected to read ''Jan. 27 & 28.''

§ 20.107 [Corrected]

1. On page 58332 footnote (3) is corrected to read, ''Harvests of trumpeter swans will be limited by quotas established in the September 27, 2000, **Federal Register** (65 FR 58152). When it has been determined that the quota of trumpeter swans allotted to Nevada and Utah will have been filled, the season for taking of any swan species in the respective State will be closed by either the Director upon giving public notice through local information media at least 48 hours in advance of the time and date of closing, or by the State through State regulations with such notice and time (not less than 48 hours) as they deem necessary.''

§ 20.109 [Corrected]

1. On page 58332 under the heading *Extended seasons, limits, and hours for taking migratory game birds by falconry,* the second introductory paragraph is corrected to read ''Hawking hours are one-half hour before sunrise until sunset, except as otherwise restricted by State regulations. Area descriptions were published in the August 23, 2000, (65 FR 51496) and September 27, 2000, (65 FR 58152) **Federal Register**s.''

Dated: December 15, 2000.

Kenneth L. Smith,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 01–372 Filed 1–4–01; 8:45 am]

BILLING CODE 4310–55–P

Proposed Rules

Federal Register
Vol. 66, No. 4
Friday, January 5, 2001

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 212

[INS. No. 1696–95]

RIN 1115–AD96

Establishing Criteria for Determining Countries Whose Citizens Are Ineligible for the Transit Without Visa (TWOV) Program

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Proposed rule.

SUMMARY: The Transit Without Visa (TWOV) program allows the Immigration and Naturalization Service (Service), acting jointly with the Department of State, to waive the passport and visa requirement for aliens from certain countries who request immediate and continuous transit privileges through the United States. This rule proposes to amend Service regulations by removing the list of those countries that are ineligible to participants in the TWOV program from the regulation. In its place the Service proposes to publish and update the list of countries that are ineligible to participate in the TWOV Program by **Federal Register** notice. This rule also sets forth a non-exhaustive list of factors that may be considered in determining those countries whose citizens or nationals are ineligible for the TWOV program.

The criteria established in this rule will allow the Service to identify ineligible countries and provide for a regular review of all countries to determine their eligibility for participation in the TWOV program.

DATES: Written comments must be submitted on or before March 6, 2001.

ADDRESSES: Please submit written comments, in triplicate, to the Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, 425 I Street, NW., Room 5307, Washington, DC 20536. To ensure proper handling please reference INS No. 1696–95 on your correspondence. Comments are available for public inspection at the above address by calling (202) 514–3048 to arrange for an appointment.

FOR FURTHER INFORMATION CONTACT: Robert Hutnick, Assistant Chief Inspector, Inspections Division, Immigration and Naturalization Service, 425 I Street, NW., Room 4064, Washington, DC 20536, telephone (202) 616–7499.

SUPPLEMENTARY INFORMATION:

What Is the Authority for Participation in the TWOV Program?

Section 212(d)(4)(C) of the Immigration and Nationality Act (Act) provides authority for the Attorney General acting jointly with the Secretary of State to waive nonimmigrant visa requirements for aliens who are proceeding in immediate and continuous transit through the United States and are using a carrier which has entered into a contract with the Service authorized under section 233(c) of the Act. This contract is an Immediate and Continuous Transit Agreement, Form I–426, also known as a TWOV Agreement.

What Changes Are Proposed in This Rule?

This rule proposes to amend § 212.1(f)(2) by removing the list of countries ineligible to participate in the TWOV program (see Department of State regulation published elsewhere in this issue of the **Federal Register**). Instead, the Service, in conjunction with the Department of State, is proposing to publish and update the list of countries whose citizens or nationals are ineligible to participate in the TWOV Program by notice published in the **Federal Register**. This rule also sets forth the authority of the Service and the Department of State to designate citizens or nationals of certain countries to be ineligible to participate in the TWOV program. It also provides a non-exhaustive list of factors to be considered in determining whether citizens or nationals of a particular country should not be eligible for participation in the TWOV program.

How Will Citizens From Ineligible Countries Know They Are Ineligible for the TWOV Programs?

The Service and the Department of State will compile a revised list of countries ineligible for the TWOV privilege and from time to time, will publish this list as a notice in the **Federal Register**. The Service and Department of State will review this list periodically and publish by notice in the **Federal Register** any additions or deletions. The list will be made available upon written request to the Service's Headquarters Office of Inspections or on the Service's website.

What Other Changes Is the Service Making in This Proposed Rule?

This rule also proposes to amend § 212.1(f)(1) by revising the reference to section ''238(d)'' of the Act to read ''233(c)''. This is a necessary conforming change to reflect the current provision of law, as amended by the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, which grants the Attorney General the power to enter into contracts with transportation lines to guarantee the passage through the United States in immediate and continuous transit of aliens destined for foreign countries.

Regulatory Flexibility Act

The Commissioner of the Immigration and Naturalization Service, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule governs whether a citizen or national from a participant country may use the TWOV program. These aliens are not considered small entities as that term is defined under in 5 U.S.C. 601(6).

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million or more in any 1 year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

This rule is not considered by the Department of Justice, Immigration and Naturalization Service, to be a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review. Accordingly, the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

Executive order 13132

This rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive order 12988 Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

List of Subjects in 8 CFR Part 212

Administrative practice and procedure, Aliens, Passports and Visas.

Accordingly, part 212 of chapter I of title 8 of the Code of Federal Regulations is proposed to be amended as follows:

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

1. The authority citation for part 212 continues to read as follows:

Authority: 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1187, 1225, 1226, 1227, 1228, 1252; 8 CFR part 2.

2. Section 212.1 is amended by:

a. Revising the reference to ''238(d)'' to read: ''233(c)'' in the first sentence in paragraph (f)(1); and by

b. Revising paragraph (f)(2), to read as follows:

§ 212.1 Documentary requirements for nonimmigrants.

* * * * *

(f) * * *

(2) *Unavailability to transit.* (i) Notwithstanding the provisions of paragraph (f)(1) of this section, the waiver of the passport and visa requirement is not available to an alien who is a citizen or national of a country designated by the Service and the Department of State to be ineligible. The Service and Department of State may designate such countries based on a variety of considerations including, but not limited to, the following:

(A) Whether citizens or nationals of the country have abused the transit without visa privilege in the past;

(B) Whether citizens or nationals of the country have a high nonimmigrant visa refusal rate;

(C) Whether there is an insurrection or instability in the country, such that citizens or nationals of the country should apply for nonimmigrant visas to ensure that they are not intending immigrants;

(D) Whether a significant number of citizens or nationals of the country are linked to terrorist activity, narcotics trafficking, or international criminal activity;

(E) Whether the President has issued a proclamation under section 212(f) of the Act suspending or restricting the entry of citizens or nationals of the country; or,

(F) Whether the country poses significant security concerns.

(ii) By notice in the **Federal Register**, the Service, acting jointly with the Department of State, shall review periodically and publish an updated list of countries ineligible for transit without visa privileges.

(iii) A list of countries whose citizens or nationals are ineligible for TWOV privileges will be maintained by the Service's Headquarters Office of Inspections and is available upon written request.

Dated: December 21, 2000.

Mary Ann Wyrsch,

Acting Commissioner, Immigration and Naturalization Service.

[FR Doc. 01–355 Filed 1–4–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–284–AD]

RIN 2120–AA64

Airworthiness Directives; Various Transport Category Airplanes Equipped With Certain Air Traffic Control (ATC) Transponders Manufactured by Rockwell Collins

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to various transport category airplanes equipped with certain Mode C air traffic control (ATC) transponders manufactured by Rockwell Collins, Inc. This proposal would require testing each transponder; replacing certain parts in any transponder which fails the initial test and performing additional test(s); and making repairs, as necessary so that the transponder passes the test. This proposal is prompted by reports that indicate that the equipment used to conduct earlier tests of certain transponders did not detect certain malfunctions. An airplane equipped with such malfunctioning transponders could transmit inaccurate data concerning its altitude to a nearby airplane equipped with the traffic alert and collision avoidance system (TCAS II), causing the TCAS II to issue an erroneous resolution advisory to the pilot. The actions specified by the proposed AD are intended to prevent transmission of inaccurate data concerning altitude from one airplane to another, which could cause the pilot receiving the data to change course, either ascending or descending, and possibly lead to a mid-air collision or near mid-air collision.

DATES: Comments must be received by February 20, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–284–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the

Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain ''Docket No. 2000–NM–284–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Rockwell Collins, Inc., 400 Collins Road NE; Cedar Rapids, Iowa 52498. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Peter Skaves, Aerospace Engineer, ANM–111, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2795; fax (425) 227–1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket. Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2000–NM–284–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–284–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Related Rulemaking

AD 99–23–22

On November 4, 1999, the FAA issued AD 99–23–22, amendment 39–11418 (64 FR 61493, November 12, 1999), applicable to various transport category airplanes equipped with Mode C air traffic control (ATC) transponders with single Gillham code altitude input. That action was prompted by reports of eleven incidents, each of which involved an airplane equipped with Mode C transponders and a second nearby airplane equipped with the traffic alert and collision avoidance system (TCAS II). In these incidents, the airplane equipped with the Mode C transponders transmitted inaccurate data regarding its altitude to the other airplane. AD 99–23–22 required repetitive tests to detect discrepancies of the transponders and other equipment associated with transmission of an airplane's altitude—aincluding the air data computer and certain wiring connections. The AD also required repairs, if necessary, and reports of the findings (both positive and negative) of the initial and the repetitive tests to the FAA. The actions required by that AD were intended to prevent an airplane equipped with one or two malfunctioning Mode C ATC transponders from transmitting such inaccurate altitude data to a nearby airplane equipped with TCAS II, causing the TCAS II to issue an erroneous resolution advisory to the pilot to ascend or descend to avoid the other airplane. Such an incident could result in a decrease of separation between the two airplanes, possibly leading to a mid-air collision or a near mid-air collision.

AD 99–23–22 R1

On December 10, 1999, the FAA issued AD 99–23–22 R1, amendment 39–11473 (64 FR 70181, December 16, 1999), to extend certain compliance times and limit the applicability of AD 99–23–22.

AD 99–23–22 R2

On April 7, 2000, the FAA issued AD 99–23–22 R2, amendment 39–11686 (65 FR 21133, April 20, 2000), to rescind AD 99–23–22 R1, because test data collected since issuance of AD 99–23–22 R1 demonstrated that repetitive tests of the transponders, air data computer, and certain wiring connections were no longer necessary. Approximately 8 percent of the tests indicated that the Mode C transponders were transmitting erroneous altitude data. Of the tests that indicated a malfunction, over 50 percent were caused by failure of the transponders rather than failure of the air data computer or the wiring connections. Many of the transponders that failed were of a particular type manufactured by Rockwell Collins, Inc. The FAA concluded, on the basis of those results, that continued repetitive tests on the subject airplane models were unnecessary, since the corrective actions had been accomplished on all transport category airplanes identified in AD 99–23–22 and AD 99–23–22 R1. In addition, the FAA determined that the repetitive tests required by AD 99–23–22 R1 could result in increased or accelerated component wear, which could contribute to malfunctioning of the Mode C ATC transponders, resulting in transmission of additional inaccurate data concerning the altitude of an airplane.

Since Issuance of AD 99–23–22 R2

In the preamble to AD 99–23–22 R2, the FAA indicated that the agency was conducting further reviews to determine whether there was a systemic failure of the transponders. The FAA added that it might consider further rulemaking to address problems with the Mode C ATC transponder. Since the issuance of AD 99–23–22 R2, Rockwell Collins, Inc., the manufacturer of the transponders, has advised that use of more sensitive testing equipment is detecting a higher malfunction rate in Mode C transponders than had been detected earlier. This finding suggests the need for further testing of certain Rockwell Collins Mode C ATC transponders, including those which had been tested previously and had apparently been functioning properly.

On May 25, 2000, Rockwell Collins, Inc. issued Service Information Letter (SIL) 00–1, which pertained to the 621A–3 transponder (with part number 522–2703–XXX). The document, subtitled ''621A–3 Transponder Overhaul Manual Test Equipment Modification Recommendation,'' indicates that some operators using ATC ramp tester model number 601 (ATC–

601) to verify performance of Mode C transponders with single Gillham encoded altitude input were experiencing a high reject rate of the 621A–3 transponders manufactured by Rockwell Collins, Inc. The service letter states that the ATC–601 ramp tester is capable of detecting out-of-tolerance errors in the framing pulse width, whereas the ATC–600 ramp tester previously used to test the transponders did not detect these pulse width errors.

Explanation of Relevant Service Information

Rockwell Collins, Inc. has issued temporary revisions to the 621A–3 ATC Transponder Overhaul Manual with Illustrated Parts List to provide a more rigorous performance test of the Mode C ATC transponders. The revisions are Temporary Revision No. 34–44–00–38, dated April 20, 2000, and Temporary Revision No. 34–44–00–39, dated May 23, 2000.

Rockwell Collins, Inc. SIL 00–1 refers to Rockwell Collins Service Bulletin 621A–3–34–21, Revision 1, dated November 14, 1975, which provides information on modification of the transponder by replacing the transmitter tube and resistor.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of the same type design, the proposed AD would require testing each transponder; replacing the transmitter tube and the resistor in any transponder which fails the initial test and performing additional test(s); and making repairs, as necessary, so that the transponder passes the test. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition.

Cost Impact

There are approximately 800 airplanes with transponders with the affected part in the worldwide fleet. The FAA estimates that approximately 400 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 4 work hours per airplane to accomplish the proposed test, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $96,000, or $240 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by the following new airworthiness directive (AD):

Transport Category Airplanes: Docket 2000–NM–284–AD.

Applicability: Transport category airplanes, certificated in any category, equipped with Rockwell Collins Mode C 621A–3 Air Traffic Control (ATC) transponder(s), part number (P/N) 522–2703–XXX (where XXX is any series number).

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent transmission of inaccurate data concerning altitude from one airplane to another, which could cause the pilot receiving the data to change course, either ascending or descending, and possibly lead to a mid-air collision or near mid-air collision, accomplish the following:

Testing

(a) Within 6 months after the effective date of this AD: Perform a pulse width test to detect malfunctions of any Mode C 621A–3 ATC transponder(s) equipped with P/N 522–2703–XXX, where XXX is any part number, in accordance with Rockwell Collins Air Transport Systems Overhaul Manual with Illustrated Parts List, Temporary Revision No. 34–44–00–38, dated April 20, 2000.

Replacement

(b) If the pulse width test required by paragraph (a) of this AD detects malfunction of a transponder: Prior to further flight, replace the transmitter tube and resistor, in accordance with Rockwell Collins Service Bulletin 621A–3–34–21, Revision 1, dated November 14, 1975, and repeat the pulse width test specified in paragraph (a) of this AD.

Repair

(c) If the follow-up pulse width test required by paragraph (b) of this AD detects malfunction of a transponder: Prior to further flight, repair the transponder, air data computer, or wiring connections between them, in accordance with the applicable Mode C transponder component maintenance manual and airplane maintenance manual. If the repair information is not available in the applicable manual, prior to further flight, repair the transponder in accordance with a method approved by the Manager, Airplane and Flight Crew Interface Branch, ANM–111, FAA, Transport Airplane Directorate.

Note 2: The airplane may be operated in accordance with the provisions and limitations specified in the FAA-approved Master Minimum Equipment List (MMEL), provided that only one Mode C transponder on the airplane is inoperative.

Reporting Requirements

(d) Submit a report of the results (both positive and negative) of the tests required by paragraph (a) and (b) of this AD to: Peter Skaves, Aerospace Engineer, ANM–111, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; fax (425) 227–1320. The report must be submitted within 60 days from the time of the transponder test. It must include the part number of the Mode ''C'' transponder(s) and whether corrective action was required. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

Alternative Methods of Compliance

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Airplanes and Flight Crew Interface Branch, ANM–111. Operators shall submit their requests through an appropriate FAA Principal Maintenance or Avionics Inspector, who may add comments and then send it to the Manager, Airplane and Flight Crew Interface Branch, ANM–111.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Manager, Airplane and Flight Crew Interface Branch, ANM–111.

Special Flight Permits

(f) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on December 29, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–341 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NM–371–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model DHC–8–100, –200, and –300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking; reopening of comment period.

SUMMARY: This document revises an earlier proposed airworthiness directive (AD), applicable to certain Bombardier Model DHC–8–100, –200, and –300 series airplanes, that continues to require a one-time detailed visual inspection to detect damage of the ladder plates and access cover areas of the upper surface of the wings, repair, if necessary, and installation of new O-ring seals. That proposal was prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. This new action revises the inspection requirements of the proposed rule by correcting a reference to a repair manual. The actions specified by this new proposed AD are intended to prevent damage of the upper wing ladder plates, which could result in displacement of the adjacent channel seals and consequent reduced lightning strike protection of the fuel tanks.

DATES: Comments must be received by January 30, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 99–NM–371–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain ''Docket No. 99–NM–371–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garrett Boulevard, Downsview, Ontario M3K 1Y5, Canada. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: James E. Delisio, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256–7521; fax (516) 568–2716.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 99–NM–371–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 99–NM–371–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD), applicable to certain Bombardier Model DHC–8–100, –200, and –300 series airplanes, was

published as a notice of proposed rulemaking (NPRM) in the **Federal Register** on February 10, 2000 (65 FR 6565). That NPRM would have required a one-time detailed visual inspection to detect damage of the ladder plates and access cover areas of the upper surface of the wings, repair, if necessary, and installation of new O-ring seals. That NPRM was prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority.

Comments

Due consideration has been given to the comments received in response to the original NPRM:

Requests to Correct a Reference to a Bombardier Repair Manual

One commenter requests correcting a reference to a repair manual in the original NPRM. That commenter states that the limits for correcting fretting corrosion are included in the Generic Structural Repair Schemes Manual PSM 1–8–3RS instead of in the Structural Repair Manual, as cited in paragraphs (a)(2) and (a)(3) of the original NPRM. A second commenter agrees with the first commenter's statements.

The FAA concurs that Generic Structural Repair Schemes Manual PSM 1–8–3RS is one of the correct references for specifying the limits for correcting fretting and corrosion. A second appropriate reference is Generic Structural Repair Schemes Manual PSM 1–82–3RS (Chapter 57 Contents and Repair Index). We point out that Bombardier Service Bulletin 8–57–41, Revision 'C' dated August 4, 2000, cites both of those references. In light of this, we have added both references in paragraphs (a)(2) and (a)(3) of this supplemental NPRM.

Requests To Change the Revision Level of the Service Bulletin

Two commenters state that the original NPRM should cite Bombardier Service Bulletin 8–57–41, Revision ''B'', dated December 22, 1999, instead of Revision ''A'', dated July 28, 1999. One of the commenters adds that Revision ''B'' includes procedures for inspecting the long-range fuel tanks.

Although the FAA does not concur that Revision ''B'' of the service bulletin should be cited, we have cited a later revision of the service bulletin, Revision ''C'', in this supplemental NPRM. Revision ''C'' includes additional changes and corrections to earlier revisions of the service bulletin, adds additional work for the operators, and revises the inspection and installation procedures for long-range fuel tanks. We have changed the reference in paragraph (a) of this supplemental NPRM to cite Revision ''C'' of the service bulletin.

Requests To Extend the Compliance Time

Two commenters request extending the compliance time for the one-time detailed visual inspection and the corrective actions specified by the original NPRM. Both commenters state that the compliance time of 60 days is too restrictive and will result in airplanes being removed from service for an extended downtime. They also consider that a 60-day compliance time would cause particular problems for U.S. operators with large fleets of Model DHC–8 series airplanes. One of the commenter suggests extending the compliance time to 12 months, and adds that its 10-year service history shows that no significant instances of corrosion or fretting occurred on its airplanes with the larger O-ring seals installed. That same commenter adds that Canadian airworthiness directive CF–99–20 specified a compliance time of 5 months for a much smaller fleet. The second commenter suggests that the action specified by the original NPRM be accomplished at the next maintenance period when the fuel tanks are accessed.

The FAA partially concurs with the commenters' requests to extend the compliance time. Analysis of the data sent by both commenters, which includes long-term service history, shows that the use of larger O-ring seals has not presented a serious problem in the U.S. fleet. For these reasons, we have extended the compliance time from 60 days to 9 months after the effective date of this AD, or at the next maintenance period during which the fuel tanks are accessed, whichever occurs earlier.

We consider that such an extension will avoid grounding airplanes unnecessarily, while ensuring timely replacement of the seals. We have revised paragraph (a) of this proposed AD accordingly.

Requests To Allow the Use of Alternative Solvents

One commenter states that the previously referenced service bulletin specifies the use of solvents that typically are not available [or are not approved] for use in the United States. The commenter suggests that the original NPRM should allow operators to use other appropriate solvents that do not pose significant safety hazards for maintenance personnel. This would avoid requiring operators to request an alternative method of compliance (AMOC) for using other appropriate solvents. A second commenter agrees with the first commenter's statements.

The FAA concurs with the commenters' suggestions to allow operators to make repairs using alternative solvents that are approved per standard industry maintenance practices without having to request an AMOC. We have added **Note 3** in this proposed AD to notify operators of such an alternative.

Explanation of Applicability

The Canadian airworthiness directive specifies, for certain Model DHC–8 series airplanes, serial numbers 003 through 543. However, the service bulletin specifies serial numbers 003 through 528 and 531, and clarifies that the specified modification will be incorporated before delivery on applicable Model DHC–8 series airplanes, having serial numbers 529, 530, and 532 through 543. For this reason, the applicability of this supplemental NPRM parallels the effectivity of the service bulletin.

Conclusion

Since the scope of the originally proposed rule has been expanded, the FAA has determined that it is necessary to reopen the comment period to provide additional opportunity for public comment.

Cost Impact

There are approximately 516 Model DHC–8–100, –200, and –300 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 235 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 6 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $84,600, or $360 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Bombardier, Inc. (Formerly de Havilland, Inc.): Docket 99–NM–371–AD.

Applicability: Model DHC–8–100, –200, and –300 series airplanes, having serial numbers 003 through 528 inclusive and 531; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent damage of the upper wing ladder plates, which could result in displacement of the adjacent channel seals and consequent reduced lightning strike protection of the fuel tanks, accomplish the following:

Inspection and Repair

(a) Within 9 months or at the next maintenance period during which the fuel tanks are accessed after the effective date of this AD, whichever occurs earlier: Perform a one-time detailed visual inspection to detect damage (i.e., fretting and/or corrosion) of the ladder plates and access cover areas of the upper surface of the wings per paragraph III.A., III.B., or III.C., as applicable, of the Accomplishment Instructions of Bombardier Service Bulletin 8–57–41, Revision 'C', dated August 4, 2000.

Note 2: For the purposes of this AD, a detailed visual inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc. may be used. Surface cleaning and elaborate access procedures may be required.''

(1) If no damage is detected, prior to further flight, install new 0.103-inch-diameter O-ring seals per paragraph III.A., III.B., or III.C., as applicable, of the Accomplishment Instructions of the service bulletin.

(2) If any damage is detected that is within the limits specified in Generic Structural Repair Schemes Manual PSM 1–8–3RS or PSM 1–82–3RS (Chapter 57 Contents and Repair Index), before further flight, repair the damage per Generic Structural Repair Schemes Manual PSM 1–8–3RS or PSM 1–82–3RS (Chapter 57 Contents and Repair Index), and install new 0.103-inch-diameter O-ring seals per paragraph III.A., III.B., or III.C., as applicable, of the Accomplishment Instructions of the service bulletin.

(3) If any damage is detected that is outside the limits specified in Generic Structural Repair Schemes Manual PSM 1–8–3RS or PSM 1–82–3RS (Chapter 57 Contents and Repair Index), before further flight, repair per a method approved by the Manager, New York Aircraft Certification Office (ACO), FAA, and install new 0.103-inch-diameter O-ring seals.

Note 3: Although the Bombardier service bulletin includes references to solvents that are not available for use in the United States, operators may use appropriate substitute solvents per standard industry maintenance practices.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York ACO, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

Special Flight Permits

(c) Special flight permits may be issued per §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 5: The subject of this AD is addressed in Canadian airworthiness directive CF–99–20, dated July 20, 1999.

Issued in Renton, Washington, on December 29, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–342 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–13–U

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Regs. Nos. 4 and 16]

RIN 0960–AE97

Federal Old-Age, Survivors and Disability Insurance and Supplemental Security Income for the Aged, Blind, and Disabled; Scheduling Video Teleconference Hearings Before Administrative Law Judges

AGENCY: Social Security Administration (SSA).

ACTION: Notice of proposed rulemaking.

SUMMARY: We propose to revise our rules to allow us to schedule video teleconference (VTC) hearings before administrative law judges (ALJs). We also propose to revise our rules so that if we schedule a VTC hearing for someone who does not want one, we will schedule a traditional, in-person hearing; that is, a hearing where all participants are at the same location. We also will schedule an in-person hearing if an individual objects to an expert witness testifying by VTC. We are proposing these revisions to provide us with greater flexibility in scheduling and holding hearings, to improve hearing process efficiency and to extend

another service delivery option to our customers.

DATES: To be sure that your comments are considered, we must receive them no later than March 6, 2001.

ADDRESSES: Comments should be submitted in writing to the Commissioner of Social Security, P.O. Box 17703, Baltimore, MD 21235–7703; sent by telefax to (410) 966–2830; sent by e-mail to regulations@ssa.gov; or delivered to the Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise Building, 6401 Security Boulevard, Baltimore, MD 21235–6401 between 8 a.m. and 4:30 p.m. on regular business days. Comments may be inspected during these hours by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Georgia E. Myers, Regulations Officer, Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–3632 or TTY 1–800–988–5906, for information about this notice. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet web site, Social Security Online, at www.SSA.gov.

SUPPLEMENTARY INFORMATION:

Background

Nationally, over 500,000 requests for a hearing before an ALJ are filed with us each year. Hearings have traditionally been held with all participants (the party(ies) to the hearing, the ALJ, and, as appropriate, the representative, medical and/or vocational expert witness(es), or a translator) present at the same location: either a hearing office or a remote hearing location. (To accommodate those individuals who do not live near a hearing office ALJs hold hearings at remote hearing locations which are generally at least 75 miles from a hearing office.) Approximately 40 percent of hearings are held at remote hearing locations.

To make travel to remote hearing locations as cost effective as possible, hearing offices wait until they have a sufficient number of requests for hearing to schedule a full day or, if travel to a remote hearing location requires an overnight stay, more than one day of hearings. Because of the need to accrue a docket, ALJs travel to some remote hearing locations infrequently. Because many remote hearing locations are in less-populous areas, it can be difficult to find an appropriate expert witness(es), which may further delay scheduling a hearing. ALJs also travel from their assigned hearing offices to assist other hearing offices when the need arises.

Whether to conduct hearings at remote locations or assist other hearing offices, the time ALJs spend traveling could be used to perform other adjudicatory responsibilities.

In 1996 we published Social Security Ruling (SSR) 96–10p, Electronic Service Delivery (61 FR 68808). In SSR 96–10p, we explained that we planned to explore ways for our customers to do business with us electronically. We also explained that we would not require customers to do business with us electronically, but that we would use technology to provide options for different service deliveries. Video teleconferencing was one of the technologies we identified as having the potential to serve our customers better. (A video teleconference provides real-time transmission of audio and video between two or more locations and permits individuals to see, hear, and speak with each other as though they were at the same location.)

We recently completed tests in which we conducted video teleconference hearings between the Huntington, West Virginia, hearing office and its Prestonburg, Kentucky, remote location; the Albuquerque, New Mexico, hearing office and its El Paso, Texas, remote location; and the West Des Moines, Iowa, hearing office with tie-in to the Iowa Communications Network (ICN). (The ICN is a statewide network that places video teleconferencing facilities within about 20 miles of most Iowa residents.) We asked individuals to participate in the tests, but did not schedule a VTC hearing until we received an individual's written concurrence.

All three sites had some equipment problems, particularly at the beginning of the tests. Although we rescheduled delayed hearings as quickly as possible, some representatives advised their clients not to elect a video teleconference hearing based on their initial experiences, especially in the Albuquerque-El Paso and Huntington-Prestonburg tests. In those two tests, an individual who elected a video teleconference hearing still had to travel to a remote hearing location; the same remote hearing location to which he or she would have had to travel for an in-person hearing. Thus, although having a video teleconference hearing at either of these sites had the potential to provide a more expeditious hearing, there was no travel benefit to the individual. Because participation rates at Huntington-Prestonburg and Albuquerque-El Paso were low we have not attempted to draw inferences about customer service or satisfaction from these tests.

Our experience was very different in Iowa, where we were not limited to using an established remote hearing location but had the benefit of the wide-ranging ICN. In Iowa, no one electing a video teleconference hearing had to travel more than about 20 miles from his or her home to have a hearing. The participation rate for the Iowa test was over 40 percent; that is, of the individuals to whom we offered a hearing, over 40 percent agreed to have, and had, a video teleconference hearing.

SSA surveyed participants from the three tests to assess customer satisfaction with video teleconference hearings. A large percentage of the Iowa respondents rated the VTC hearing as ''convenient'' or ''very convenient,'' and overall service as either ''good'' or ''very good.'' Test data show that processing time for video teleconference hearings was substantially less than for in-person remote location hearings during the same time period, and that the ratio of hearings held to hearings scheduled was significantly higher for video teleconference hearings than for in-person hearings. Being able to hold hearings as scheduled increases our efficiency because we do not have to recontact the individual to determine why he or she did not appear at a scheduled hearing nor reschedule the hearing (which can be time consuming, especially when an expert witness(es) has been scheduled to testify). Further, an ALJ does not spend time waiting for someone who does not appear, as would be the case in an in-person remote location hearing.

Based on all these factors—customer satisfaction, ability to provide more timely hearings, savings in ALJ travel time, faster case processing, and higher ratio of hearings held to hearings scheduled—we decided that conducting hearings by VTC is an efficient service delivery alternative. We also decided that scheduling a VTC hearing, rather than asking someone to elect a VTC hearing, would improve hearing office efficiency and would permit us to provide faster access to a hearing for some individuals.

We plan to begin using video teleconferencing facilities in the servicing area of a hearing office when the Associate Commissioner of the Office of Hearings and Appeals determines that hearings can be conducted more efficiently in that area by video teleconferencing than by conducting traditional, in-person hearings where all the participants are

at the same location. We foresee initially scheduling VTC hearings where we could provide faster access to a hearing because otherwise:

- We would need to accrue a docket for a remote hearing location.
- An ALJ would need to travel to assist another hearing office.
- An expert witness(es) or appropriate medical specialist(s) would not be available for a hearing location. (In such a case, all participants could be at different locations; for example, the ALJ at a hearing office, the individual at a remote hearing site or another hearing office, and the expert witness(es) at a third location.)

At first, we plan to locate most remote VTC hearing sites either in space where we have a long-term lease or in another federal building. We are investigating sharing VTC facilities with other federal agencies and states, and, if we can ensure privacy, we may eventually rent commercial space to expand VTC hearings as a service delivery option. Regardless of the type of facility, we will make certain that:

- The individual has the same access to the hearing record as he or she would have with an in-person hearing.
- There is a means of transmitting and receiving additional evidence between all locations and all participants.
- An assistant is present at the VTC hearing site to operate the equipment and provide other help, as required.
- The audio/video transmission is secure and the individual's privacy is protected.

We will follow the same procedures for audiotaping VTC hearings that we do for in-person hearings but will not videotape VTC hearings. We also will not necessarily schedule a VTC hearing for someone who asks for one. In many locations, especially in the near term, we may not have the capability to accommodate the request. As access to video teleconferencing expands, we will accommodate requests for VTC hearings as space and time permit. Should there be a problem with the VTC equipment, before or during a hearing, we will reschedule the hearing as we do now when unforeseen circumstances require us to reschedule a hearing: at the earliest time possible based on the request for hearing filing date.

Despite the fact that conducting hearings by VTC has the potential to improve customer service, under these regulations we will not require anyone to have a VTC hearing who does not want one. Under these regulations, if an individual objects to having a VTC hearing or to an expert witness(es) testifying by VTC we will schedule an in-person hearing. In both instances, we will reschedule the hearing at the earliest time possible based on the request for hearing filing date.

To ensure that an individual fully understands the right to decline to have a VTC hearing or to have an expert witness(es) testify by VTC, the notice of VTC hearing will clearly state:

- What it means to have a VTC hearing.
- That we have scheduled a VTC hearing for him or her or have scheduled an expert witness(es) to testify by VTC.
- That we will schedule an in-person hearing if the individual tells us he or she does not want a VTC hearing or does not want an expert witness(es) to testify by VTC.
- How to tell us if he or she does not want to have a VTC hearing or does not want an expert witness(es) to testify by VTC.

We will collect information about VTC hearings to ensure that individuals:

- Understand they are not required to have a VTC hearing or to have an expert witness(es) testify by VTC.
- Know how to tell us if they do not want a VTC hearing or do not want an expert witness(es) to testify by VTC.
- Receive a full and fair hearing.

and to ensure that:

- There is no significant difference in the outcome of in-person and VTC hearings.
- We maintain a high degree of accuracy in our hearing decisions.

Proposed Changes

We propose to revise 20 CFR 404.929 and 416.1429 to state that we will conduct hearings by VTC, in addition to in-person hearings at which all participants are present at the same location. We propose to revise 20 CFR 404.936 and 416.1436 to state that we may schedule a VTC hearing or an expert witness(es) to testify by Video teleconference, and if we do, and an individual tells us he or she wants an in-person hearing, we will schedule an in-person hearing. We propose to revise 20 CFR 404.938 and 416.1438 to state that if we schedule your hearing as a video teleconference hearing, or if we schedule a witness to appear at the hearing by video teleconference, the notice of hearing will provide information about a VTC hearing and about how you can tell us that you do not want to have a VTC hearing or have an expert witness testify by video teleconference.

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** on the Internet site for the Government Printing Office, *http://www.access.gpo.gov/su docs/aces/aces140.html.* It is also available on SSA's Internet site, SSA Online, at http://*www.ssa.gov.*

Clarity of the Proposed Rules

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make the rules easier to understand. For example:

—Have we organized the material to suit your needs?
—Are the requirements in the rules clearly stated?
—Do the rules contain technical language or jargon that isn't clear?
—Would a different format (grouping and order of sections, use of headings, paragraphing) make the rules easier to understand?
—Would more (but shorter) sections be better?
—Could we improve clarity by adding tables, lists, or diagrams?
—What else could we do to make the rules easier to understand?

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed rules do not meet the criteria for a significant regulatory action under Executive Order 12866. Therefore, they are not subject to OMB review.

Regulatory Flexibility Act

We certify that these proposed rules, if promulgated, will not have a significant economic impact on a substantial number of small entities because they affect only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

There is a reporting requirement in proposed §§ 404.936 and 416.1436, which requires individuals to notify us if they object to having their hearing conducted or an expert witness(es) testify by video teleconference. As required by the Paperwork Reduction Act of 1995, we have submitted a copy of this information collection requirement to OMB for its review. Other organizations and individuals desiring to submit comments on the information collection requirements

should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Room 3208, Washington, DC 20503, ATTENTION: OMB Desk Officer for SSA.

The public reporting burden for this collection of information is estimated to average 10 minutes per response. This includes the time it will take to understand what is needed, gather the necessary facts, and provide the information needed. Under our near-term capability to conduct video teleconference hearings, we expect there will be 3,000 requests per year. Therefore, the annual reporting burden is expected to be 500 hours. If you have any comments or suggestions on this estimate, write to the Social Security Administration, ATTN: Reports Clearance Officer, 1–A–21 Operations Building, Baltimore, MD 21235.

SSA is soliciting comments from the public in order to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology (*e.g.,* permitting electronic submission of responses).

- (Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.003, Social Security-Special Benefits for Persons Aged 72 and Over; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income.)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Aged, Blind, Disability benefits, Old-age, survivors and disability insurance, Reporting and recordkeeping requirements, Social security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Dated: December 22, 2000.

Kenneth S. Apfel,

Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend subpart J of part 404 and subpart N of part 416 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

1. The authority citation for subpart J of part 404 continues to read as follows:

Authority: Secs. 201(j), 204(f), 205(a), (b), (d)-(h), and (j), 221, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 404(f), 405(a), (b), (d)-(h), and (j), 421, 425, and 902(a)(5); 31 U.S.C. 3720A; sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)-(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note).

2. Section 404.929 is revised to read as follows:

§ 404.929 Hearing before an administrative law judge—general.

If you are dissatisfied with one of the determinations or decisions listed in § 404.930 of this part you may request a hearing. The Associate Commissioner for Hearings and Appeals, or his or her delegate, shall appoint an administrative law judge to conduct the hearing. If circumstances warrant, the Associate Commissioner, or his or her delegate, may assign your case to another administrative law judge. At the hearing you may appear in person (that is, where all participants are present at the same location) or by video teleconference, submit new evidence, examine the evidence used in making the determination or decision under review, and present and question witnesses. The administrative law judge who conducts the hearing may ask you questions. He or she shall issue a decision based on the hearing record. If you waive your right to appear at the hearing, either in person or by video teleconference, the administrative law judge will make a decision based on the evidence that is in the file and any new evidence that may have been submitted for consideration.

3. Section 404.936 is revised to read as follows:

§ 404.936 Time, place and type of hearing before an administrative law judge.

(a) We may schedule your hearing by video teleconference if we determine that it is more efficient to do so and the technology is available in the area where you live. You will receive a written notice if we schedule a video teleconference hearing for you. The notice will tell you that if you do not want the hearing held by video teleconference, you must tell us so as explained in the notice, and we will schedule an in-person hearing for you.

(b) If we determine that it is not more efficient or if the technology is not available in the area where you live, we will schedule an in-person hearing for you. The administrative law judge sets the time and the place for the in-person hearing.

(c) The administrative law judge may change the site and/or time of the videoconference hearing or the time and place of the in-person hearing, if it is necessary. After sending you reasonable notice of the proposed action, the administrative law judge may adjourn or postpone the hearing or reopen it to receive additional evidence any time before he or she notifies you of a hearing decision. We hold hearings in the 50 States, the District of Columbia, American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico and the Virgin Islands.

(d) If you object to the site and/or time of your scheduled videoconference hearing or to the time and/or place of your scheduled in-person hearing, you must notify the administrative law judge at the earliest possible opportunity before the time set for the hearing. You must state the reason for your objection and state the site and/or time you want the videoconference hearing to be held or the time and/or place you want the in-person hearing to be held. If at all possible, the request should be in writing. The administrative law judge will change the site and/or time of the videoconference hearing or the time and/or place of the in-person hearing if you have good cause, as determined under paragraphs (e)(1) and (2) of this section. Section 404.938 of this part provides procedures we will follow when you do not respond to a notice of hearing.

(e) The administrative law judge will find good cause for changing the site and/or time of your scheduled videoconference hearing or the time and/or place of your scheduled in-person hearing, and will reschedule your hearing if your reason is one of the following circumstances and is supported by the evidence:

(1) You or your representative are unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing.

(f) In determining whether good cause exists in circumstances other than those set out in paragraph (e) of this section, the administrative law judge will consider your reason for requesting the change, the facts supporting it, and the impact of the proposed change on the efficient administration of the hearing process. Factors affecting the impact of the change include, but are not limited to, the effect on the processing of other scheduled hearings, delays which might occur in rescheduling your hearing, and whether any prior changes were granted to you. Examples of such other circumstances, which you might give for requesting a change in the time or place of the hearing, include, but are not limited to, the following:

(1) You have attempted to obtain a representative but need additional time;

(2) Your representative was appointed within 30 days of the scheduled hearing and needs additional time to prepare for the hearing;

(3) Your representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing;

(4) A witness who will testify to facts material to your case would be unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained;

(5) Transportation is not readily available for you to travel to the hearing;

(6) You live closer to another hearing location; or

(7) You are unrepresented, and you are unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) which you may have.

4. Section 404.938 is revised to read as follows:

§ 404.938 Notice of hearing before an administrative law judge.

(a) *General notice information:* After your hearing has been scheduled, we will mail notice of the hearing to you at your last known address, or give the notice to you by personal service, unless you have indicated in writing that you do not wish to receive this notice. The notice will be mailed or served at least 20 days before the hearing. The notice of hearing will contain a statement of the specific issues to be decided and tell you that you may designate a person to represent you during the proceedings. The notice will also contain an explanation of the procedures for requesting a change in the time or place of your hearing, a reminder that if you fail to appear at your scheduled hearing without good cause, the ALJ may dismiss your hearing request and other information about the scheduling and conduct of your hearing. If you or your representative do not acknowledge receipt of the notice of hearing, we will attempt to contact you for an explanation. If you tell us that you did not receive the notice of hearing, an amended notice will be sent to you by certified mail. See § 404.936 of this part for the procedures we will follow in deciding whether the time of your scheduled videoconference hearing or the time or place of your scheduled in-person hearing will be changed if you do not respond to the notice of hearing.

(b) *Hearing via video conferencing:* If we determine that it is more efficient and if the technology is available in the area where you live, we will schedule your hearing as a video teleconference. If we schedule a video teleconference for you, your notice, in addition to the information in paragraph (a) of this section, will also clearly state what it means to have a video teleconference hearing and if we have scheduled an expert witness(es) to testify by video teleconference. The notice will contain an explanation of how to let us know if you do not want to have a video teleconference hearing or do not want an expert witness to testify via video teleconference. We will schedule an in-person hearing for you if you tell us that you do not want a video teleconference hearing or do not want an expert witness to testify via video teleconference. Your notice will also contain an explanation of the procedures for requesting a change in the time of your scheduled videoconference hearing.

(c) *For a hearing in-person before an administrative law judge:* If we determine that it is not more efficient or if the technology is not available in the area where you live, an in-person hearing will be scheduled for you.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND AND DISABLED

Subpart N—[Amended]

5. The authority citation for subpart N of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b); 31 U.S.C. 3720A.

6. Section 416.1429 is revised to read as follows:

§ 416.1429 Hearing before an administrative law judge—general.

If you are dissatisfied with one of the determinations or decisions listed in § 416.1430 of this part you may request a hearing. The Associate Commissioner for Hearings and Appeals, or his or her delegate, shall appoint an administrative law judge to conduct the hearing. If circumstances warrant, the Associate Commissioner, or his or her delegate, may assign your case to another administrative law judge. At the hearing you may appear in person (that is, where all participants are present at the same location) or by video teleconference, submit new evidence, examine the evidence used in making the determination or decision under review, and present and question witnesses. The administrative law judge who conducts the hearing may ask you questions. He or she shall issue a decision based on the hearing record. If you waive your right to appear at a hearing, either in person or by video teleconference, the administrative law judge will make a decision based on the evidence that is in the file and any new evidence that may have been submitted for consideration.

7. Section 416.1436 is revised to read as follows:

§ 416.1436 Time, place and type of hearing before an administrative law judge.

(a) We may schedule your hearing by video teleconference if we determine that it is more efficient to do so and the technology is available in the area where you live. You will receive a written notice if we schedule a video teleconference hearing for you. The notice will tell you that if you do not want the hearing held by video teleconference, you must tell us so as explained in the notice, and we will schedule an in-person hearing for you.

(b) If we determine that it is not more efficient or if the technology is not available in the area where you live, we will schedule an in-person hearing for you. The administrative law judge sets the time and the place for the in-person hearing.

(c) The administrative law judge may change the site and/or time of the videoconference hearing or the time and place of the in-person hearing, if it is necessary. After sending you reasonable notice of the proposed action, the administrative law judge may adjourn or postpone the hearing or reopen it to receive additional evidence any time before he or she notifies you of a hearing decision. We hold hearings in the 50 States, the District of Columbia, and the Northern Mariana Islands.

(d) If you object to the site and/or time of your scheduled videoconference hearing or to the time and/or place of your scheduled in-person hearing, you must notify the administrative law judge

at the earliest possible opportunity before the time set for the hearing. You must state the reason for your objection and state the site and/or time you want the videoconference hearing to be held or the time and/or place you want the in-person hearing to be held. If at all possible, the request should be in writing. The administrative law judge will change the site and/or time of the videoconference hearing or the time and/or place of the in-person hearing if you have good cause, as determined under paragraphs (e)(1) and (2) of this section. Section 416.1438 of this part provides procedures we will follow when you do not respond to a notice of hearing.

(e) The administrative law judge will find good cause for changing the site and/or time of your scheduled videoconference hearing or the time and/or place of your scheduled in-person hearing, and will reschedule your hearing if your reason is one of the following circumstances and is supported by the evidence:

(1) You or your representative are unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing.

(f) In determining whether good cause exists in circumstances other than those set out in paragraph (e) of this section, the administrative law judge will consider your reason for requesting the change, the facts supporting it, and the impact of the proposed change on the efficient administration of the hearing process. Factors affecting the impact of the change include, but are not limited to, the effect on the processing of other scheduled hearings, delays which might occur in rescheduling your hearing, and whether any prior changes were granted to you. Examples of such other circumstances, which you might give for requesting a change in the time or place of the hearing, include, but are not limited to, the following:

(1) You have attempted to obtain a representative but need additional time;

(2) Your representative was appointed within 30 days of the scheduled hearing and needs additional time to prepare for the hearing;

(3) Your representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing;

(4) A witness who will testify to facts material to your case would be unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained;

(5) Transportation is not readily available for you to travel to the hearing;

(6) You live closer to another hearing location; or

(7) You are unrepresented, and you are unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) which you may have.

8. Section 416.1438 is revised to read as follows:

§ 416.1438 Notice of a hearing before an administrative law judge.

(a) *General notice information:* After your hearing has been scheduled, we will mail notice of the hearing to you at your last known address, or give the notice to you by personal service, unless you have indicated in writing that you do not wish to receive this notice. The notice will be mailed or served at least 20 days before the hearing. The notice of hearing will contain a statement of the specific issues to be decided and tell you that you may designate a person to represent you during the proceedings. The notice will also contain an explanation of the procedures for requesting a change in the time or place of your hearing, a reminder that if you fail to appear at your scheduled hearing without good cause, the ALJ may dismiss your hearing request and other information about the scheduling and conduct of your hearing. If you or your representative do not acknowledge receipt of the notice of hearing, we will attempt to contact you for an explanation. If you tell us that you did not receive the notice of hearing, an amended notice will be sent to you by certified mail. See § 416.1436 of this part for the procedures we will follow in deciding whether the time of your scheduled videoconference hearing or the time or place of your scheduled in-person hearing will be changed if you do not respond to the notice of hearing.

(b) *Hearing via video conferencing:* If we determine that it is more efficient and if the technology is available in the area where you live, we will schedule your hearing as a video teleconference. If we schedule a video teleconference for you, your notice, in addition to the information in paragraph (a) of this section, will also clearly state what it means to have a video teleconference hearing and if we have scheduled an expert witness(es) to testify by video teleconference. The notice will contain an explanation of how to let us know if you do not want to have a video teleconference hearing or do not want an expert witness to testify via video teleconference. We will schedule an in-person hearing for you if you tell us that you do not want a video teleconference hearing or do not want an expert witness to testify via video teleconference. Your notice will also contain an explanation of the procedures for requesting a change in the time of your scheduled videoconference hearing.

(c) *For a hearing in-person before an administrative law judge:* If we determine that it is not more efficient or if the technology is not available in the area where you live, an in-person hearing will be scheduled for you.

[FR Doc. 01–319 Filed 1–4–01; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 3533]

RIN 1400–AA48

Bureau of Consular Affairs; Visas: Documentation of Nonimmigrants Under the Immigration and Nationality Act—Amendment of Transit Without Visa (TWOV) List.

AGENCY: Bureau of Consular Affairs, Department of State.

ACTION: Proposed rule, with request for comments.

SUMMARY: This rule proposes to amend the Department of State regulation that allows for a waiver of the visa and passport requirement under the Transit Without Visa (TWOV) Program authorized under section 233 of the Immigration and Nationality Act (INA) for citizens of certain countries who are in immediate and continuous transit through the United States. The Department proposes to remove from the current regulation the list of countries ineligible to participate in the TWOV Program and to publish a separate list which will be updated and published periodically.

This rule also sets forth the criteria, which among other factors, will be used in determining which countries will be ineligible for the TWOV privilege.

DATES: Interested persons should submit comments on or before March 6, 2001.

ADDRESSES: Submit comments, in duplicate, to the Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, D.C. 20522–0113.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Office, Room L603–C, SA–1, Department of State, Washington, D.C. 20520–0106, (202) 663–1204; or e-mail: *odomhe@state.gov.*

SUPPLEMENTARY INFORMATION:

Background/Waiver Authority

Section 212(d)(4)(C) of the Immigration and Nationality Act (INA) provides authority for the Secretary of State, acting jointly with the Attorney General, to waive the passport and/or visa requirement for a nonimmigrant who is in immediate and continuous transit through the United States and is using a carrier that has entered into a Transit Without Visa (TWOV) Agreement as provided in INA 233(c).

Since TWOV does not involve the issuance of a visa, the Department's role in the day-to-day administration of the TWOV program is minimal.

Therefore, the Department's regulation at 22 CFR 41.2(i), for the most part, is merely a restatement of the INS regulation on the same subject. The Department does become involved, however, in designating those countries whose citizens are ineligible for the TWOV privilege.

How will the Regulation Be Changed

Amending the List of Ineligible Countries

The current regulation provides a list of countries whose citizens are ineligible for the TWOV privilege. The Department proposes to amend this regulation by removing the list of ineligible countries from the regulation and afterward, periodically, to publish such a list it in a **Federal Register** Notice. This will allow the Department to review and publish any revised list more frequently and more easily.

Determining Ineligibility to TWOV

In this rule the Department proposes criteria which will be used in determining for the purpose of publishing the list in the **Federal Register** those countries whose citizens will be ineligible to transit without visa. The list is not exhaustive. Other relevant factors, as determined by the Department and the INS, may be considered as well.

Based on these criteria, and other relevant factors, the Department and INS intend to periodically compile an updated list of countries whose citizens are ineligible for the waiver privilege and to publish the list in a notice in the **Federal Register**.

What Is the Authority for Allowing or Prohibiting Transit Without Visa

Section 212(d)(4)(C) of the Immigration and Nationality Act (INA) provides the authority for the Secretary of State, acting jointly with the Attorney General, to waive the passport and/or visa requirement for a nonimmigrant who is in immediate and continuous transit through the United States and is using a carrier that has entered into a Transit Without Visa (TWOV) Agreement as provided in INA 233(c)

Who Determines Which Countries Can Transit Without a Visa

Since TWOV does not involve the issuance of a visa, the Department's role in the day-to-day administration of the TWOV program is minimal. Therefore, the Department's regulation at 22 CFR 41.2(i), for the most part, is merely a restatement of the INS regulation on the same subject. The Department does become involved, however, in the designation of those countries whose citizens are ineligible to utilize the TWOV. The current regulation provides a list of ineligible countries.

What Criteria Will Be Considered in Determining Eligibility to TWOV

Along with other factors which the Department and the INS have determined relevant, the Department will consider.

(i) Whether citizens of the country have abused this waiver privilege in the past;

(ii) Whether citizens of the country have a high nonimmigrant visa refusal rate;

(iii) Whether there is insurrection or instability in the country, such that citizens of the country should apply for visas to ensure that they are not intending immigrants;

(iv) Whether a significant number of citizens of the country are linked to terrorist activity, narcotics trafficking, or international criminal activity;

(v) Whether the President has issued a proclamation under section INA 212(f) pertaining to citizens of the country; or

(vi) Whether the country poses significant security concerns.

Proposed Rule

How Will the Department of State Amend Its Regulations

The Department of State proposes to amend 22 CFR 41.2(i) by removing the list of countries for which the transit without visa privilege is not available. After consideration of the criteria outlined above, the Department and the INS propose to publish and update a list of countries whose citizens are ineligible for the TWOV privilege.

What Effect Will This Rule Have on Aliens Currently Excluded From the TWOV Privilege

This is a proposed rule and, therefore, does not affect aliens currently excluded from the TWOV privilege. Any changes to the list of ineligible aliens will take effect upon publication of a final rule. At the time of publication of the final rule, the Department will also publish a separate notice designating those countries whose citizens are ineligible for the TWOV privilege. The Department and the INS will review and update this list periodically.

Administrative Procedure Act

The Department is publishing this rule as a proposed rule, with a 60-day provision for public comments.

Regulatory Flexibility Act

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

The Department of State does not consider this rule, to be a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, and the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various

levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping requirements. The information collection requirement (Form OF–156) contained by reference in this rule was previously approved for use by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

List of Subjects in 22 CFR Part 41

Aliens, Nonimmigrants, Passports and visas.

In view of the foregoing, the Department amends 22 CFR as follows:

PART 41—[AMENDED]

1. The authority citation continues to read as follows:

Authority: 8 U.S.C. 1104; Pub. L. 105–277, 112 Stat. 2681 *et. seq.*

2. Section 41.2 is amended by revising paragraph (i)(2) and adding paragraph (i)(3) to read as follows:

§ 41.2 Waiver by Secretary of State and Attorney General of passport and/or visa requirements for certain categories of nonimmigrants.

* * * * *

(i) *Aliens in immediate transit without visa (TWOV).* * * *

(2) Notwithstanding the provisions of paragraph (i)(1) of this section, an alien is not eligible for this waiver if the alien is a national of a country whose citizens the Secretary of State and/or the Attorney General have designated to be ineligible to transit the United States without a visa. The Department and the INS may designate such nationalities based on a variety of considerations including, but not limited to, the following:

(i) Whether citizens of the country have abused this waiver privilege in the past;

(ii) Whether citizens of the country have a high nonimmigrant visa refusal rate;

(iii) Whether there is insurrection or instability in the country, such that citizens of the country should apply for visas to ensure that they are not intending immigrants;

(iv) Whether a significant number of citizens of the country are linked to terrorist activity, narcotics trafficking, or international criminal activity;

(v) Whether the President has issued a proclamation under section INA 212(f) pertaining to citizens of the country; or

(vi) Whether the country poses significant security concerns.

(3) The Secretary of State, acting jointly with the Attorney General, will review periodically and publish in the **Federal Register** an updated list of countries whose citizens they have determined are ineligible to transit without visa.

Dated: September 15, 2000.

Maura Harty,

Acting Assistant Secretary for Consular Affairs.

[FR Doc. 01–357 Filed 1–4–01; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–116468–00]

RIN 1545–AY43

Minimum Cost Requirement Permitting the Transfer of Excess Assets of a Defined Benefit Pension Plan to a Retiree Health Account

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed Income Tax Regulations relating to the minimum cost requirement under section 420, which permits the transfer of excess assets of a defined benefit pension plan to a retiree health account. Pursuant to section 420(c)(3)(E), these proposed regulations provide that an employer who significantly reduces retiree health coverage during the cost maintenance period does not satisfy the minimum cost requirement of section 420(c)(3). In addition, these proposed regulations clarify the circumstances under which an employer is considered to have significantly reduced retiree health coverage during the cost maintenance period. This document also provides a notice of public hearing on these regulations.

DATES: Written or electronic comments must be received by March 6, 2001. Requests to speak (with outlines of oral comments to be discussed) at the public hearing scheduled for March 15, 2001, must be received by February 21, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–116468–00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–116468–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at http://www.irs.gov/tax__regs/regslist.html.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Vernon S. Carter or Janet A. Laufer, (202) 622–6060; concerning submissions, Treena Garrett, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The Revenue Reconciliation Act of 1990 (Pub. L. 101–508)(104 Stat. 1388), section 12011, added section 420 of the Internal Revenue Code (Code), a temporary provision permitting certain qualified transfers of excess pension assets from a non-multiemployer defined benefit pension plan to a health benefits account (defined as an account established and maintained under section 401(h) of the Code (401(h) account)) that is part of the plan.[1] One of the conditions of a qualified section 420 transfer was that the employer satisfy a maintenance of effort requirement in the form of a ''minimum cost requirement'' under which the employer was required to maintain employer-provided retiree health expenditures for covered retirees, their spouses, and dependents at a minimum dollar level for a 5-year cost maintenance period, beginning with the taxable year in which the qualified transfer occurs.

The Uruguay Round Agreements Act (Pub. L. 103–465)(108 Stat. 4809)

[1] Section 420(a)(1) and (2) provide that the trust that is part of the plan is not treated as failing to satisfy the qualification requirements of section 401 (a) or (h) of the Code, and no amount is includable in the gross income of the employer maintaining the plan, solely by reason of such transfer. Also, section 420(a)(3) provides that a qualified transfer is not treated as either an employer reversion for purposes of section 4980 or a prohibited transaction for purposes of section 4975.

In addition, Title I of the Employee Retirement Income Security Act of 1974 (88 Stat. 829), as amended (ERISA), provides that a qualified transfer pursuant to section 420 is not a prohibited transaction under ERISA (ERISA section 408(b)(13)) or a prohibited reversion of assets to the employer (ERISA section 403(c)(1)). ERISA also provides certain notification requirements with respect to such qualified transfers.

(December 8, 1994), extended the availability of section 420 through December 31, 2000. In conjunction with the extension, Congress modified the maintenance of effort rules for plans transferring assets for retiree health benefits so that employers could take into account cost savings realized in their health benefit plans. As a result, the focus of the maintenance of effort requirement was shifted from health costs to health benefits. Under this ''benefit maintenance requirement,'' which applied to qualified transfers made after December 8, 1994, an employer had to maintain substantially the same level of employer-provided retiree health coverage for the taxable year of the transfer and the following 4 years. The level of coverage required to be maintained was based on the coverage provided in the taxable year immediately preceding the taxable year of the transfer.

The Tax Relief Extension Act of 1999 (title V of H.R. 1180, the Ticket to Work and Work Incentives Improvement Act of 1999) (Pub. L. 106–170,113 Stat 1860) (TREA–99) extended section 420 through December 31, 2005. In conjunction with this extension, the minimum cost requirement was reinstated as the applicable ''maintenance of effort'' provision (in lieu of requiring the maintenance of the level of coverage) for qualified transfers made after December 17, 1999. Because the minimum cost requirement relates to per capita cost, an employer could satisfy minimum cost requirement by maintaining the average cost even though the employer defeats the purpose of the maintenance of effort requirement by reducing the number of people covered by the health plan. In response to concerns regarding this possibility, TREA–99 also added section 420(c)(3)(E), which requires the Secretary of the Treasury to prescribe such regulations as may be necessary to prevent an employer who significantly reduces retiree health coverage during the cost maintenance period from being treated as satisfying the minimum cost requirement of section 420(c)(3). If the minimum cost requirement of section 420(c)(3) is not satisfied, the transfer of assets from the pension plan to the 401(h) account is not a ''qualified transfer'' to which the provisions of section 420(a) apply.

Explanation of Provisions

These proposed regulations would provide that the minimum cost requirement of section 420(c)(3) is not met if the employer significantly reduces retiree health coverage during the cost maintenance period. The proposed regulations would measure whether this occurs by looking at the number of individuals (retirees, their spouses, and dependents) who lose coverage during the cost maintenance period as a result of employer actions, measured on both an annual basis and a cumulative basis.

In determining whether an employer has significantly reduced retiree health coverage, the regulations would provide that the employer does not satisfy the minimum cost requirement if the percentage decrease in the number of individuals provided with applicable health benefits that is attributable to employer action exceeds 10% in any year, or if the sum of the annual percentage decreases during the cost maintenance period exceeds 20%. The 10% annual limit would not apply to a taxable year that begins before February 5, 2001.

The regulations would provide a broad definition of employer action, including not only plan amendments but also situations in which other employer actions, such as the sale of all or part of the employer's business, operate in conjunction with the existing plan terms to have the indirect effect of ending an individual's coverage. The definition of employer action would include plan amendments that are executed before the cost maintenance period but take effect during the cost maintenance period, unless the amendment occurred before the later of December 18, 1999, and 5 years before the start of the cost maintenance period.

The regulations contain a special rule that addresses situations in which an employer adopts plan terms that establish eligibility for health coverage for some individuals, but provide that those same individuals lose health coverage upon the occurrence of a particular event or after a stated period of time. In those cases, an individual is not counted as having lost health coverage by reason of employer action merely because that individual's coverage ends upon the occurrence of the event or after the stated period of time.

Under the proposed regulation, when an individual's coverage ends by reason of a sale of all or part of the employer's business, the individual is counted as an individual losing coverage by reason of employer action. The proposed regulation contains no exceptions from this rule even if the buyer provides coverage for such individuals (on the implicit assumption that the buyer rarely undertakes to provide such coverage to retirees in these transactions). Comments are specifically requested as to (1) the circumstances, if any, in which buyers commonly provide the seller's retirees, and their spouses and dependents, with health coverage following a corporate transaction, and (2) in such cases, criteria that should apply to the replacement coverage in determining whether to treat those individuals as not having lost coverage.

Proposed Effective Date

The regulations are proposed to be applicable to transfers of excess pension assets on or after December 18, 1999.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and, because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department specifically request comments on the clarity of the proposed rule and how it may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for March 15, 2001, beginning at 10 a.m. in the IRS Auditorium, Seventh Floor, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the 10th Street entrance, located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** portion of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments must submit written comments and an outline of the topics to be discussed and time to be devoted to each topic (a signed original and eight (8) copies) by February 21, 2001. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal authors of these regulations are Vernon S. Carter and Janet A. Laufer, Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and Treasury Department participated in their development.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding a new entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805, 26 U.S.C. 420(c)(3)(E) * * *

Par. 2. Section 1.420–1 is added to read as follows:

§ 1.420–1 Significant reduction in retiree health coverage during the cost maintenance period.

(a) *In general.* Notwithstanding section 420(c)(3)(A), the minimum cost requirements of section 420(c)(3) are not met if the employer significantly reduces retiree health coverage during the cost maintenance period.

(b) *Significant reduction*—(1) *In general.* An employer significantly reduces retiree health coverage during the cost maintenance period if, for any taxable year during the cost maintenance period, either —

(i) The employer-initiated reduction percentage for that taxable year exceeds 10%; or

(ii) The sum of the employer-initiated reduction percentages for that taxable year and all prior taxable years during the cost maintenance period exceeds 20%.

(2) *Special rule for certain taxable years.* Notwithstanding paragraph (b)(1)(i) of this section, an employer will not be treated as significantly reducing retiree health coverage for a taxable year that begins before February 5, 2001, merely because the employer-initiated reduction percentage for that taxable year exceeds 10%.

(3) *Employer-initiated reduction percentage.* The employer-initiated reduction percentage for any taxable year is the fraction B/A, expressed as a percentage, where

A = The total number of individuals (retired employees plus their spouses plus their dependents) receiving coverage for applicable health benefits as of the day before the first day of the taxable year.

B = The total number of individuals included in A whose coverage for applicable health benefits ended during the taxable year by reason of employer action.

(4) *Employer action*—(i) *General rule.* For purposes of paragraph (b)(3) of this section, an individual's coverage for applicable health benefits ends during a taxable year by reason of employer action, if on any day within the taxable year, the individual's eligibility for applicable health benefits ends as a result of a plan amendment or any other action of the employer (*e.g.,* the sale of all or part of the employer's business) that, in conjunction with the plan terms, has the effect of ending the individual's eligibility. An employer action is taken into account for this purpose regardless of when the employer action actually occurs (*e.g.,* the date the plan amendment is executed), except that employer actions occurring before the later of December 18, 1999, and the date that is 5 years before the start of the cost maintenance period are disregarded.

(ii) *Special rule.* Notwithstanding paragraph (b)(4)(i) of this section, coverage for an individual will not be treated as having ended by reason of employer action merely because such coverage ends under the terms of the plan if those terms were adopted contemporaneously with the provision under which the individual became eligible for retiree health coverage.

(c) *Definitions.* The following definitions apply for purposes of this section:

(1) *Applicable health benefits.* Applicable health benefits means applicable health benefits as defined in section 420(e)(1)(C).

(2) *Cost maintenance period.* Cost maintenance period means the cost maintenance period as defined in section 420(c)(3)(D).

(d) *Examples.* The following examples illustrate the application of this section:

Example 1. (i) Employer W maintains a defined benefit pension plan that includes a 401(h) account and permits qualified transfers that satisfy section 420. The number of individuals receiving coverage for applicable health benefits as of the day before the first day of Year 1 is 100. In Year 1, Employer W makes a qualified transfer under section 420. There is no change in the number of individuals receiving health benefits during Year 1. As of the last day of Year 2, applicable health benefits are provided to 99 individuals, because 2 individuals became eligible for coverage due to retirement and 3 individuals died in Year 2. During Year 3, Employer W amends its health plan to eliminate coverage for 5 individuals, 1 new retiree becomes eligible for coverage and an additional 3 individuals are no longer covered due to their own decision to drop coverage. Thus, as of the last day of Year 3, applicable health benefits are provided to 92 individuals. During Year 4, Employer W amends its health plan to eliminate coverage under its health plan for 8 more individuals, so that as of the last day of Year 4, applicable health benefits are provided to 84 individuals. During Year 5, Employer W amends its health plan to eliminate coverage for 8 more individuals.

(ii) There is no significant reduction in retiree health coverage in either Year 1 or Year 2, because there is no reduction in health coverage as a result of employer action in those years.

(iii) There is no significant reduction in Year 3. The number of individuals whose health coverage ended during Year 3 by reason of employer action (amendment of the plan) is 5. Since the number of individuals receiving coverage for applicable health benefits as of the last day of Year 2 is 99, the employer-initiated reduction percentage for Year 3 is 5.05% (5/99), which is less than the 10% annual limit.

(iv) There is no significant reduction in Year 4. The number of individuals whose health coverage ended during Year 4 by reason of employer action is 8. Since the number of individuals receiving coverage for applicable health benefits as of the last day of Year 3 is 92, the employer-initiated reduction percentage for Year 4 is 8.70% (8/92), which is less than the 10% annual limit. The sum of the employer-initiated reduction percentages for Year 3 and Year 4 is 13.75%, which is less than the 20% cumulative limit.

(v) In Year 5, there is a significant reduction under paragraph (b)(1)(ii) of this section. The number of individuals whose health coverage ended during Year 5 by reason of employer action (amendment of the plan) is 8. Since the number of individuals receiving coverage for applicable health benefits as of the last day of Year 4 is 84, the employer-initiated reduction percentage for Year 5 is 9.52% (8/84), which is less than the 10% annual limit. However, the sum of the employer-initiated reduction percentages for Year 3, Year 4, and Year 5 is 5.05% + 8.70% + 9.52% = 23.27%, which exceeds the 20% cumulative limit.

Example 2. (i) Employer X maintains a defined benefit pension plan that includes a 401(h) account and permits qualified transfers that satisfy section 420. X also provides lifetime health benefits to employees who retire from Division A as a result of a plant shutdown, no health benefits to employees who retire from Division B, and lifetime health benefits to all employees who

retire from Division C. In 2000, X amends its health plan to provide coverage for employees who retire from Division B as a result of a plant shutdown, but only for the 2-year period coinciding with their severance pay. Also in 2000, X amends the health plan to provide that employees who retire from Division A as a result of a plant shutdown receive health coverage only for the 2-year period coinciding with their severance pay. A plant shutdown that affects Division A and Division B employees occurs in 2000. The number of individuals receiving coverage for applicable health benefits as of the last day of 2001 is 200. In 2002, Employer X makes a qualified transfer under section 420. As of the last day of 2002, applicable health benefits are provided to 170 individuals, because the 2-year period of benefits ends for 10 employees who retired from Division A and 20 employees who retired from Division B as a result of the plant shutdown that occurred in 2000.

(ii) There is no significant reduction in retiree health coverage in 2002. Coverage for the 10 retirees from Division A who lose coverage as a result of the end of the 2-year period is treated as having ended by reason of employer action, because coverage for those Division A retirees ended by reason of a plan amendment made after December 17, 1999. However, the terms of the health plan that limit coverage for employees who retired from Division B as a result of the 2000 plant shutdown (to the 2-year period) were adopted contemporaneously with the provision under which those employees became eligible for retiree coverage under the health plan. Accordingly, under the rule provided in paragraph (b)(4)(ii) of this section, coverage for those 20 retirees from Division B is not treated as having ended by reason of employer action. Thus, the number of individuals whose health benefits ended by reason of employer action in 2002 is 10. Since the number of individuals receiving coverage for applicable health benefits as of the last day of 2001 is 200, the employer-initiated reduction percentage for 2002 is 5% (10/200), which is less than the 10% annual limit.

(e) *Effective date.* This section is applicable December 18, 1999, for qualified transfers occurring on or after that date.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–249 Filed 1–4–01; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

RIN 1024–AC82

Special Regulations, Areas of the National Park System

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: The National Park Service (NPS) is proposing to amend regulations specific to Rocky Mountain National Park that designate snowmobile routes inside the park. The routes currently designated are inconsistent with the protection of the resources and values of this park, management objectives, with the requirements of two executive orders, and NPS general regulations that govern snowmobile use in the National Park System. This amendment would eliminate three of the four routes currently designated for snowmobile use and bring the remaining route into compliance with the general regulations.

DATES: Written comments will be accepted through March 6, 2001.

ADDRESSES: Comments should be addressed to: National Park Service, Ranger Activities Division, 1849 C Street, NW., Room 7408, Washington, DC 20240. Fax (202) 208–6756. Email: WASO__Regulations@nps.gov.

FOR FURTHER INFORMATION CONTACT: Kym Hall, Regulations Program Manager, National Park Service, 1849 C Street, N.W., Room 7413, Washington, DC 20240. Telephone: (202) 208–4206; Fax: (202) 208–6756; Email: Kym__Hall@nps.gov.

SUPPLEMENTARY INFORMATION:

Background

In January 1999, the NPS received a petition for rulemaking from the Bluewater Network, representing some 60 conservation organizations, requesting that we begin immediate rulemaking to prohibit snowmobile use within units of the National Park System. To gather information on how to respond, NPS conducted a survey of those parks in which snowmobile use is currently allowed. The survey gathered information from each relevant park on such matters as the basis on which a decision was originally made to allow snowmobile use in that park; how extensive that use is; what is known about the impacts of that use on park resources and values, including the enjoyment of other visitors; and what monitoring, if any, is conducted to determine those impacts. Additionally, the NPS held a two-day snowmobile ''summit'' in January 2000 at which officials from the Department of the Interior (including the Office of the Solicitor) and the National Park Service (including all but one affected park) reviewed the snowmobile use now occurring in the National Park System. We learned through the survey and the snowmobile ''summit'' that much of the snowmobile use that occurs in the National Park System is not consistent with management objectives or the protection of park resources and value, and is not in compliance with the requirements of the two executive orders and the NPS general regulations on snowmobile use.

In April 2000, the Department and NPS publicly announced an intention to propose changes in the snowmobile use allowed in parks, to protect park resources and values, to meet management objectives and to come into compliance with the legal requirements applying to that use. Consistent with that announcement, this is a proposed regulatory action to make those changes in the park-specific regulations governing snowmobile use in Rocky Mountain National Park, by repealing the current designation of three routes in the park as open to snowmobiles. Only one of those routes is currently open to snowmobile use. For the other two, this proposal would amend the park-specific regulations to conform to previous decisions by the park management to close the routes to snowmobile use. This proposed rule will leave one route in the park, the North Supply Creek Snowmobile Access Trail, designated for snowmobile use. An environmental analysis and a draft economic analysis have been prepared.

Existing Regulations

Executive Order 11644, issued by President Nixon in 1972, provides, among other things, that snowmobile use may be allowed in the National Park System only on areas and trails designated by NPS for that purpose, and only if NPS determines that the snowmobile use on those areas and trails will not adversely affect the park's natural, aesthetic, or scenic values. It requires NPS to monitor the effects of authorized snowmobile use in parks. It also requires NPS, on the basis of the information gathered through that monitoring, to amend or rescind designations of those areas and trails open to snowmobile use as necessary to avoid adverse effects on the park's natural, aesthetic, or scenic values.

Executive Order 11989, issued by President Carter in 1977, requires NPS, whenever it determines that the use of snowmobiles will cause or is causing considerable adverse effects on the natural resources of a park, to take steps to prevent those effects, including immediately halting that use.

NPS general regulations on snowmobile use, 36 CFR 2.18(c), state that:

The use of snowmobiles is prohibited, except on designated routes and water surfaces that are used by motor vehicles or

motorboats during other seasons. Routes and waters surfaces designated for snowmobile use shall be promulgated as special regulations. Snowmobiles are prohibited except where designated and only when their use is consistent with the park's natural, cultural, scenic and aesthetic values, safety considerations, park management objectives, and will not disturb wildlife or damage park resources.

Rocky Mountain National Park currently has four routes where snowmobile use has been designated via a special regulation: the Summerland Park Snowmobile Trail; the North Supply Creek Access Snowmobile Trail (identified in the regulation as the Supply Creek Snowmobile Access Trail); sixteen miles of Trail Ridge Road, including both a plowed stretch from the Kawuneeche Visitor Center to the Timber Lake Trailhead (ten miles) that is also open to other motor vehicles and an unplowed stretch (six miles) from the Timber Lake Trailhead to Milner Pass (these stretches are identified as separate routes in the current special regulation for the park); and the Bowen Gulch Access Route. All of these routes are in the Colorado River District, or western portion, of the park.

Two of these routes, the Bowen Gulch Access Route and the Summerland Park Snowmobile Trail, are not now open to snowmobile use, since they have been closed by prior park action reflected in the Superintendent's compendium.

On the two designated trails that are open to snowmobile use, 28,417 snowmobiles entered the park in the winter of 1999–2000, making Rocky Mountain one of the parks with the highest levels of snowmobile use in the national park system. By contrast, 88 snowmobiles entered the park in 1967, the first year for which use figures are available. Approximately 85 percent of the current use occurs on the North Supply Creek Snowmobile Access Trail, a route of approximately two miles in length that provides snowmobile access to adjacent national forest lands. The remainder of the use occurs on Trail Ridge Road, which provides snowmobile access into the interior of the park.

This proposed rule would repeal the designations of all designated snowmobile routes in Rocky Mountain other than the North Supply Creek Access Trail.

Explanation of Rule

Repealing the designations of all routes except the North Supply Creek Access Trail is necessary to comply with the requirements of the applicable Executive Orders and NPS's general regulation on snowmobile use, 36 CFR 2.18, to protect park resources and values, and to meet park management objectives.

Repealing the designations of the Bowen Gulch Access Trail and the Summerland Park Snowmobile Trail is justified for the same reasons that snowmobile use has not been allowed on those routes since 1981 and 1997, respectively. The Bowen Gulch Access Route historically provided snowmobile access to adjacent national forest lands that were open to snowmobile use, but that adjacent use ended in 1980 when Congress designated the national forest lands as part of the Never Summer Wilderness. The Summerland Park Snowmobile Trail was closed in 1997, because its inaccessibility made the area difficult for park rangers to patrol and monitor; its use led to off-road snowmobile use in violation of NPS regulations; and its use led to incidents of trespass onto adjacent private lands.

Ending snowmobile use on Trail Ridge Road will reduce the adverse impacts of snowmobile noise on the natural soundscape of the park, on wildlife, and on other visitors to the park. Natural quiet will be restored to the area that extends from the Timber Lake Trailhead parking lot to Milner Pass. The long-term integrity of wilderness values in the Kawuneeche Valley in the vicinity of Trail Ridge Road will be protected and enhanced. The restored natural quiet will allow wildlife to exist in a more natural setting. Bighorn sheep that may have been avoiding Milner Pass during the winter because of noisy snowmobiles may return. The many visitors who come to Rocky Mountain in the winter seeking solitude, serenity, and tranquility (as documented by visitor use surveys) will have their enjoyment of the park enhanced.

Eliminating snowmobile use on Trail Ridge Road will also reduce air pollution in the interior of the park, eliminate any possible impacts to soils or vegetation from snowmobile use along this route, and eliminate emissions that settle onto the snow and get carried into the park's streams and lakes by snowmelt.

In addition, the dual use of the lower, plowed stretch of Trail Ridge Road by snowmobiles and other motor vehicles, on the same road surface, also presents safety concerns. The State of Colorado prohibits dual use by snowmobiles and other motor vehicles of the same road surface, on roads under state jurisdiction. On the lower stretch of Trail Ridge Road, the NPS has been allowing such dual use. Closing this stretch of road to snowmobile use is consistent with the state policy, and will improve public safety. In December 1999, there was a collision between a snowmobile and a minivan, with the snowmobile sliding on the ice and striking the van.

Continuing to allow snowmobile use on the North Supply Creek Access Trail is consistent with applicable Executive Orders, the NPS's general snowmobile regulation, the protection of park resources and values, and park management considerations.

The North Supply Creek Access Trail is a two-mile trail that provides access to adjacent national forest lands that are heavily used by snowmobiles. The first 0.87 mile of the trail within the park follows a utility corridor right of way, which is open to NPS, county, and public utility vehicles, and which is maintained as a fire access road. The remaining 1.13 miles follows the Sun Valley Road, which is a county road. This snowmobile trail provides the only safe and reasonable access between the town of Grand Lake and national forest lands west of the park that contain 17 named snowmobile routes with a total length of 92.3 miles. Limiting snowmobile use in the park to the North Supply Access Trail will limit any impacts of that use (primarily any impacts from noise) to this small portion of the park (where noise is already audible from snowmobiles in use on adjacent national forest lands).

When final, this rule would become effective for the winter use season of 2002–2003. In a consolidated appropriations bill given final Congressional approval on December 15, 2000, Congress has provided that, in promulgating any new rules to reduce snowmobile use in units of the national park system, the NPS may not establish an effective date for the reductions any earlier than the winter season of 2002–2003.

Compliance With Other Laws

Regulatory Planning and Review (E.O. 12866)

This document is a significant rule and has been reviewed by the Office of Management and Budget under Executive Order 12866.

(1) This rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities.

Nonetheless, the NPS has prepared a draft study on the economic effects of this proposal on, among others, small businesses. ''Proposed Restrictions on Snowmobile Riding in Rocky Mountain

National Park: Draft Report'' (LawGibb Group, Arcadis JSA, and Research Triangle Institute, November 2000).

This draft report indicates that the proposed regulation is expected to lead to a reduction in the number of visitor days spent by snowmobilers in Rocky Mountain in the winter, as they would no longer be able to use Trail Ridge Road. There may or may not be a reduction in visitation to the gateway community of Grand Lake, Colorado, depending on (1) how many people who used to snowmobile on Trail Ridge Road will continue to come to the area to snowmobile on other routes, and (2) whether there is an increase in other winter visitors to the park who will have a more enjoyable winter experience there without snowmobile use on Trail Ridge Road.

Examining a likely range of possible reductions in winter visitation to Grand Lake, the report indicates that the total impact on businesses in Grand Lake could range from an annual decrease of $265,800 to $728,200 in business revenues. Approximately two-thirds of any impact will be on snowmobile rental businesses, followed by lodging (17.5 percent), restaurants and bars (9.2 percent), gas and oil, souvenirs and other retail trade, and grocery businesses.

You may obtain a copy of the draft economic report by one of several ways:
—Internet: http://www.nps.gov/romo/
—By mail: Bruce Peacock, National Park Service, 1849 C Street, NW., Room 2749, Washington, DC 20240.
—By email: Bruce_Peacock@nps.gov

Public comments regarding the economic report may be submitted to Bruce Peacock at one of the addresses above.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

This rule deals specifically with Rocky Mountain National Park, which is administered solely by the NPS, and any rules regarding snowmobile use there would affect only the NPS and not other agencies.

(3) This rule does not alter the budgetary effects or entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients.

There are no budgetary constraints or funding issues associated with this rulemaking at all. This rule pertains only to the recreational uses of areas within the park.

(4) This rule may raise novel legal or policy issues.

Though this rule is but a portion of the total snowmobile use within the NPS system, the specific issue of snowmobile restrictions in any of the NPS areas has raised concerns from the public regarding policies. Generally the effect of this rulemaking would be a small percentage of change in use patterns within the park.

Regulatory Flexibility Act

The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Nonetheless, the NPS has prepared a draft study on the economic effects of this proposal on, among others, small entities. ''Proposed Restrictions on Snowmobile Riding in Rocky Mountain National Park: Draft Report'' (LawGibb Group, Arcadis JSA, and Research Triangle Institute, November 2000). Small entities potentially affected will be all six snowmobile rental shops in the Grand Lake area, and all governmental jurisdictions in the area.

For snowmobile rental shops, the proposed regulation could lead to a loss of annual revenue ranging from $159,554 to $398,885. This represents nine to 22 percent of their estimated total winter revenue. However, there appears to be excess demand for snowmobile rentals in Grand Lake, with the rental businesses typically renting all available machines on weekends, weather permitting, and during holiday weeks. This could mean that the effects on the rental shops could be less than the ranges estimated.

The town of Grand Lake does not collect a sales and use tax on snowmobile rentals. The range in reductions in winter visitation examined in the study would lead to a decline in the town's sales and use tax receipts from retail sales ranging between $2,479 and $8,430.

The NPS solicits comments on any alternative approach to the proposed regulation—such as a limitation on the number of snowmobiles that may use Trail Ridge Road, a limitation on the hours of use of such snowmobiles, a restriction on use of snowmobiles to a smaller portion of Trail Ridge Road, technical or mechanical changes to snowmobiles that could be required to reduce air and noise emissions from snowmobiles so as to enable their use on Trail Ridge Road, use fees or other market-based regulatory mechanisms, or a delay in the effective date of the regulations—that could both accomplish the objectives and fulfill the requirements of the laws, executive orders, and regulations applying to snowmobile use in the park and minimize any possible adverse economic impact of the proposed regulation on small businesses.

Additionally, we solicit comments on the potential impacts that this rule may have on small entities. We welcome comments with information regarding the number and types of entities impacted, the specific costs that may be imposed by this rule on small entities, and whether and why these impacts may be considered significant.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of $100 million or more.

This rule has been estimated to have a potential impact on small businesses (six rental shops) from approximately $160,000 to $400,000 annually.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

There are not likely to be cost increases associated with this rulemaking. The potential economic effect would be a minimal loss of revenue to small businesses and tax revenue to local governments.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S-based enterprises to compete with foreign-based enterprises.

This rule only pertains to recreational uses within a park unit and does not have effects on production between the United States and foreign entities.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector.

This rule poses regulatory requirements only on those visitors that choose to operate a snowmobile within Rocky Mountain National Park, and it does not require any additional expenditures of money by them. Potential impacts to local government could be in the loss of tax revenue estimated between $2000 and $8000 annually.

Takings (E.O. 12630)

In accordance with 12630, the rule does not have significant takings implications.

This rulemaking affects only those areas within Rocky Mountain National Park and has no effects on external ownership of lands outside the park boundary.

Federalism (E.O. 13132)

In accordance with Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

This rulemaking only affects users who choose to operate snowmobiles within the park. There are no obvious effects on the State of Colorado.

Civil Justice Reform (E.O. 12988)

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

This regulation does not require an information collection from 10 or more parties and a submission under the Paperwork Reduction Act is not required. An OMB form 83–I is not required.

National Environmental Policy Act

This rule does not constitute a major federal action significantly affecting the quality of the human environment. A draft Environmental Assessment has been completed. Copies of that assessment may be obtained through one of several methods.

—Internet: http://www.nps.gov/romo/
—By email: romo_superintendent@nps.gov
—By mail: Superintendent, Rocky Mountain National Park, 1000 U.S. Highway 36, Estes Park, Colorado 80517.

Public comments regarding the Environmental Assessment may be submitted to Rocky Mountain National Park at one of the addresses above. Public comments will be accepted at the park through January 13, 2001.

Government-to-Government Relationship with Tribes

In accordance with the president's memorandum of April 29, 1994, ''Government -to-Government Relations with Native American Tribal Governments'' (59 FR 22951) and 512 DM 2, we have evaluated potential effects on federally recognized Indian tribes and have determined that there are no potential effects.

This rulemaking would not involve any lands or resources administered by Native American Tribes. This rule only addresses routes inside the boundaries of Rocky Mountain National Park.

Clarity of This Regulation

Executive Order 12866 requires each agency to write regulations that are easy to understand. We invite your comments on how to make this rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the rule clearly stated? (2) Does the rule contain technical language or jargon that interferes with its clarity? (3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, *etc.*) aid or reduce its clarity? (4) Would the rule be easier to understand if it were divided into more (but shorter) sections? A ''section'' appears in body type and is preceded by the symbol ''§'' and a numbered heading; for example, **§ 7.7 [amended].** (5) Is the description of the rule in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the proposed rule? What else could we do to make the rule easier to understand?

Send a copy of any comments that concern how we could make this rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street NW, Washington, DC 20240. You may also e-mail the comments to this address: Exsec@ios.doi.gov

Public Participation: If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to the National Park Service, Ranger Activities Division, 1849 C Street, NW., Washington, DC 20240. You may also comment via the Internet to WASO;_Regulations@nps.gov. Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include ''Attn: 1024–AC82'' in the subject line and your name and return address in the body of your Internet message. Finally, you may hand deliver comments to Kym Hall, Regulations Program Manager, National Park Service, 1849 C Street, N.W., Room 7413, Washington DC. Our practice is to make comments, including names and addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address for the rulemaking record, which we will honor to the extent allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

List of Subjects in 36 CFR Part 7

District of Columbia, National parks, Reporting and recordkeeping requirements

Accordingly, we propose to amend Part 7 of 36 CFR as set forth below:

PART 7—SPECIAL REGULATIONS; AREAS OF THE NATIONAL PARK SYSTEM

1. The authority for Part 7 continues to read as follows:

Authority: 16 U.S.C. 1, 3, 9a, 460(q), 462(k); Sec. 7.96 also issued under D.C. Code 8–137 (1981) and D.C. Code 40–721 (1981).

§ 7.7 [Amended]

2. Revise § 7.7(e) to read as follows:

* * * * *

(e) *Snowmobiles*—(1) *On what route may I operate a snowmobile?* Snowmobiles may be operated on the North Supply Creek Snowmobile Access Trail solely for the purpose of gaining access between national forest lands on the west side of the park and the town of Grand Lake. Use of this trail for other purposes is not permitted. This trail will be marked by signs, snow poles or other appropriate means.

(2) *When may I operate a snowmobile on the North Supply Creek Snowmobile Access Trail?* The Superintendent shall determine the opening and closing dates for use of the North Supply Creek Snowmobile Access Trail each year, taking into consideration the location of wintering wildlife, appropriate snow cover, and other factors that may relate to public safety. The Superintendent will notify the public of such dates through normal news media channels. Temporary closure of this route will be initiated through the posting of appropriate signs and/or barriers. This route will be open to snowmobile travel when it is considered to be safe for travel but not necessarily free of safety hazards. Snowmobilers may travel this route with the permission of the Superintendent, but at their own risk.

Dated: December 22, 2000.

Stephen C. Saunders,

Acting Assistant Secretary, Fish and Wildlife and Parks.

[FR Doc. 01–377 Filed 1–4–01; 8:45 am]

BILLING CODE 4310–70–P

Notices

Federal Register
Vol. 66, No. 4
Friday, January 5, 2001

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Beal Mountain Mine Montana Pollution Discharge Elimination System Permit Application for Final Treatment of Process Solutions by Land Application, Beaverhead-Deerlodge National Forest, Silver Bow County, MT

AGENCY: Forest Service, USDA, and Department of Environmental Quality.

ACTION: Notice; intent to prepare environmental impact statement.

SUMMARY: The Forest Service and Montana Department of Environmental Quality will prepare an environmental impact statement on a short term water treatment proposal submitted by HB Engineering Group, Trustee for the bankrupt Beal Mountain Mine, Inc.. The Trustee proposes to treat approximately 150,000 gallons of heap leach pad process solutions using a biological treatment plant. The proposed process would need a polishing treatment step to meet State water quality standards. A Montana Pollution Discharge Elimination System (MPDES) Permit would be needed with a groundwater mixing zone to comply with Montana's Water Quality Act. The Forest Service and the Montana Department of Environmental Quality are charged to ensure reclamation of the mine site land to a stable and usable condition is accomplished. The Forest Service decision to be made is whether to approve land application of the treated process solution and whether additional treatment beyond the biological plant is needed prior to land application. The State of Montana decision to be made is whether to issue a MPDES Permit.

DATES: Comments concerning the scope of the analysis should be received in writing by January 31, 2001.

ADDRESSES: The responsible officials are Forest Supervisor Janette Kaiser, Beaverhead-Deerlodge National Forest, Dillon, MT, and Mark A. Simonich, the Director for the Montana Department of Environmental Quality, Helena, MT. To facilitate the analysis of public comments, send written comments to Jocelyn Dodge, Butte Ranger District, 1820 Meadowlark, Butte, MT 59701. Comments may be electronically submitted to jdodge@fs.fed.us.

FOR FURTHER INFORMATION CONTACT: Jocelyn Dodge, EIS Team Leader (406) 494–0246.

SUPPLEMENTARY INFORMATION: 1. The proposal is to infiltrate the treated process solution through the soil horizon for final treatment in the land application disposal (LAD) areas using a drip irrigation system. Monitoring data would be used to determine application rates, volumes, duration, monitoring and compliance points. Several systems would be operational at any time to provide maximum flexibility in land application of the treated process solution. When the proper volume has been applied, the LAD system would be relocated to another area. The agencies will decide whether to approve land application to the treated process solution and/or if additional treatment beyond the biological plant is needed for the process solution prior to land application. This document incorporates by reference the 1988 Environmental Assessment for the Beal Mountain Mine and the 1993 Environmental Impact Statement for the Beal Mountain Mine South Beal expansion.

The project area is located in Township 2N, Range 10W, Section 6.

Scoping activities to date have included a letter to citizens and groups interested in activities in the project area. No public meetings are scheduled at this time.

From the public comments received during initial scoping, the following issues have been identified: 1. Water quality; 2. Fisheries in German Gulch; and, 3. Effects on wildlife habitat and postmine safety. Alternatives will be developed based on the key issues identified after scoping.

The Beaverhead-Deerlodge National Forest and Department of Environmental Quality are joint leads in this analysis.

People may visit with agency officials at any time during the analysis and prior to the decision. Two periods are specifically designated for comments on the analysis: (1) During the scoping process, and, (2) during the draft EIS period.

During the scoping process, the Forest Service is seeking additional information and comments from individuals or organizations who may be interested in or affected by the proposed action, and Federal, State and local agencies. Written comments and suggestions on this action are invited, particularly in terms of identification of issues and alternative development.

The draft EIS should be available for review in March, 2001, and the final EIS is scheduled for completion in May, 2001.

The comment period on the draft environmental impact statement will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes it is important to give reviewers notice at this early stage of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. Vermont *Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement.

Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. (Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.).

The responsible officials will make the decision on this proposal after considering comments and responses, environmental consequences discussed in the Final EIS, applicable laws, regulations, and policies. The Forest Service decision and reasons for the decision will be documented in a Record of Decision.

Dated: December 21, 2000.

Janette S. Kaiser,

Forest Supervisor.

[FR Doc. 01–286 Filed 1–4–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Helena National Forest Travel Plan, Helena National Forest, Broadwater, Lewis and Clark, Meagher and Powell Counties, MT

AGENCY: Forest Service, USDA.

ACTION: Notice; Extension of comment period.

SUMMARY: On December 1, 2000 the Forest Service published a Notice of Intent to prepare an Environmental Impact Statement on a proposal to update travel management on approximately 390,000 acres of National Forest lands on the Townsend, Helena and Lincoln Ranger Districts. These 390,000 acres are the remaining lands that have not been subject to recent motorized travel management decisions or have decisions pending. The project covers three separate areas in the Blackfoot, Divide/Little Blackfoot and the South Belts areas. Motorized travel activities in these areas are presently subject to the June 30, 1994 Helena National Forest Travel Plan. The original NOI specified that comments should be received by January 5, 2001. The comment period will be extended to January 31, 2001.

DATES: Comments concerning the proposal and scope of the analysis should be received in writing by January 31, 2001.

ADDRESSES: Send written comments to USDA Forest Service, Helena National Forest, 2880 Skyway Drive, Helena, MT 59601.

FOR FURTHER INFORMATION CONTACT: Tom Andersen, Team Leader, (406) 449–5201, ext 277.

The responsible official is Thomas J. Clifford, Forest Supervisor, Helena National Forest, 2880 Skyway Drive, Helena, MT 59601.

Dated: December 21, 2000.

Thomas J. Clifford,

Helena Forest Supervisor.

[FR Doc. 01–285 Filed 1–4–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Mill-Key-Wey Timber Sales; Superior Ranger District, Lolo National Forest; Mineral County, MT

AGENCY: Forest Service, USDA.

ACTION: Notice; Revised notice of intent to prepare environmental impact statement.

SUMMARY: The Forest Service published a notice of intent to prepare an environmental impact statement (EIS) for the Mill-Key-Wey Timber sales project in the **Federal Register** (vol. 64, no. 140, doc. no. 99–18759) on July 22, 1999. That notice of intent is revised to change the schedule for completion of the draft EIS.

Forest Service policy mandates that a revised Notice of Intent be filed when there is a delay of more than six months in filing the draft EIS. Originally the draft EIS was to be released in August of 1999 and the final EIS in December of 1999. The draft EIS was completed in February of 2000 with the final EIS anticipated to be published in April of 2001.

DATES: This action is effective upon publication of this notice.

ADDRESSES: Cindy Chapman Enstrom, Superior Ranger District, Box 460, Superior, MT 59872.

FOR FURTHER INFORMATION CONTACT: Pay Partyka, EIS Team Leader, Superior Ranger District, as above, or phone: (406) 826–4314.

Authority: 40 CFR 1508.22.

Dated: December 14, 2000.

Deborah L.R. Austin,

Forest Superior.

[FR Doc. 01–292 Filed 1–4–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Oregon Coast Provincial Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Oregon Coast Provincial Advisory Committee (PAC) will meet at the Hatfield Marine Sciences Center, Room 9, Marine Sciences Drive, Newport, OR, January 18, 2001. The meeting will begin at 9 a.m. and end at 3:30 p.m. the agenda will include: a Newport subcommittee report on water use, Payments to Counties Bill S1608/HR2389, Salem Water Program Strategy, discussion of 2001 agenda topics, public comments, and round-robin information sharing. A cold lunch buffet prepared by the Angell Job Corps will be available at 11:45 a.m. The cost is $4. A fifteen-minute open public forum is scheduled at 2 p.m. Interested citizens are encouraged to attend. The committee welcomes the publics' written comments on committee business at any time.

FOR FURTHER INFORMATION CONTACT: Joni Quarnstrom, Public Affairs Specialist, Siuslaw National Forest, 541/750–7075 or write to Forest Supervisor, Siuslaw National Forest, P.O. Box 1148, Corvallis, OR 97339.

Dated: December 29, 2000.

Mary Zuschlag,

Acting Forest Supervisor.

[FR Doc. 01–308 Filed 1–4–01; 8:45 am]

BILLING CODE 3410–10–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Glen Hills Watershed, Dunn and St. Croix Counties, WI

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of a finding of no significant impact.

SUMMARY: Pursuant to Section 102(c) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Regulations (40 CFR Part 1500); and the Natural Resources Conservation Service Regulations (7 CFR Part 650); the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Glen Hills Watershed, Dunn and St. Croix Counties, Wisconsin.

FOR FURTHER INFORMATION CONTACT: Patricia S. Leavenworth, State Conservationist, Natural Resources Conservation Service, 6515 Watts Road, Suite 200, Madison, Wisconsin, 53719. Telephone (608) 276–8732.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, or national impacts on the environment. As a result of these findings, Patricia S. Leavenworth, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The project purposes are flood prevention and recreation. The planned works of improvement include the removal of one single family dwelling from the hydraulic shadow of Structure Number 2, and the enactment of a county floodplain zoning ordinance which restricts future development within the hydraulic shadow of Structure Number 2.

The Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various Federal, State, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Sheryl B. Paczwa.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register.**

Patricia S. Leavenworth,

State Conservationist.

[FR Doc. 01–287 Filed 1–4–01; 8:45 am]

BILLING CODE 3410–16–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletions from the Procurement List.

SUMMARY: This action adds to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List commodities previously furnished by such agencies.

EFFECTIVE DATE: February 5, 2001.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Louis R. Bartalot (703) 603–7740.

SUPPLEMENTARY INFORMATION: On April 21, November 3 and November 13, 2000, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (65 FR 21395, 66230 and 67714) of proposed additions to and deletions from the Procurement List:

Additions

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodities and services and impact of the additions on the current or most recent contractors, the Committee has determined that the commodities and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action will not have a severe economic impact on current contractors for the commodities and services.

3. The action will result in authorizing small entities to furnish the commodities and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services proposed for addition to the Procurement List.

Accordingly, the following commodities and services are hereby added to the Procurement List:

Commodities

Protector and Sleeve Transparencies
7510–00–NIB–0176
7510–00–NIB–0177
7510–00–NIB–0178

Services

Administrative Services (Religious Services Technician), Department of Justice, Federal Bureau of Prisons, Federal Correctional Institution, Cumberland, Maryland.

Janitorial/Custodial, Department of the Treasury, Federal Law Enforcement Training Center, Bldgs. 161, 163, 165, 167, Glynco, Georgia.

These actions do not affect current contracts awarded prior to the effective date of these additions or options that may be exercised under those contracts.

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action will not have a severe economic impact on future contractors for the commodities and services.

3. The action will result in authorizing small entities to furnish the commodities and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services deleted from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the commodities listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4. Accordingly, the following commodities are hereby deleted from the Procurement List:

Commodities

Applicator, Wax
M.R. 922
Cutlery, Heavy Duty
M.R. 533
M.R. 534
M.R. 535

Louis R. Bartalot,

Deputy Director (Operations).

[FR Doc. 01–351 Filed 1–4–01; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletion

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled

ACTION: Proposed Additions to and Deletion from Procurement List

SUMMARY: The Committee is proposing to add to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete commodity previously furnished by such agencies.

Comments Must Be Received on or Before: February 5, 2001.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Louis R. Bartalot (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Additions

If the Committee approves the proposed addition, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action will result in authorizing small entities to furnish the commodities and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information. The following commodities and services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodities

Chalkboard
- 6910–04–000–4482
- 6910–04–000–4485

NPA: Tuscola County Community Mental Health Services, Caro, Michigan

Undershirt, White
- 8420–00–543–6645
- 8420–00–543–6647
- 8420–00–543–6648
- 8420–00–543–6649
- 8420–00–543–6650

NPA: BESB Industries, West Hartford, Connecticut

Services

Base Supply Center, Fort Buchanan, Fort Buchanan, PR
NPA: Winston-Salem Industries for the Blind, Winston-Salem, North Carolina

Janitorial/Custodial

Redstone Arsenal, Basewide, Redstone Arsenal, AL
NPA: Huntsville Rehabilitation Foundation, Huntsville, Alabama

Janitorial/Custodial

Federal Building, 1520 Market Street, St. Louis, Missouri
NPA: MGI Services Corporation, St. Louis, Missouri

Janitorial/Custodial

Lewiston-Queenston and Whirlpool Rapids Bridges, Niagara Falls, New York
NPA: Niagara Frontier Vocational Rehab Center, Inc., Buffalo, New York

Janitorial/Grounds Maintenance

Volpe National Transportation Systems Center, 55 Broadway, Cambridge, Massachusetts
NPA: Work, Incorporated, North Quincy, Massachusetts

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action will result in authorizing small entities to furnish the commodities and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services proposed for deletion from the Procurement List.

The following commodity has been proposed for deletion from the Procurement List:

Commodities

Kit, Computer Maintenance
7035–01–452–9086
7045–01–315–0850
7045–01–450–8599

Louis R. Bartalot,

Deputy Director (Operations).

[FR Doc. 01–352 Filed 1–4–01; 8:45 am]

BILLING CODE 6353–01–P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Notice

AGENCY: U.S. Commission on Civil Rights.

DATE AND TIME: Friday, January 12, 2001, 8:00 a.m.

PLACE: Holiday Inn Select Hotel, 316 West Tennessee Street, Tallahassee, FL 32301.

STATUS:

Agenda

I. Approval of Agenda
II. Approval of Minutes of December 8, 2000 Meeting
III. Announcements
IV. Staff Director's Report
V. Planning Meeting for 2001
VI. Final Report Card: The Civil Rights Performance of the Clinton Administration
VII. State Advisory Committee Report
- Who is Enforcing Civil rights in Arkansas: Is There a Need for a State Civil Rights Agency?

VIII. Future Agenda Items
9:00 a.m. Hearing To Reconvene From Previous Day

CONTACT PERSON FOR FURTHER INFORMATION: Les Jin, Office of the Staff Director (202) 376–7700.

Edward A. Hailes, Jr.,

Acting General Counsel.

[FR Doc. 01–459 Filed 1–3–01; 2:12 pm]

BILLING CODE 6335–00–M

DEPARTMENT OF COMMERCE

Submission For OMB Review; Comment Request

DOC has submitted to the Office of Management and Budget (OMB) for clearance, the following proposal for an extension of a currently approved collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of Economic Analysis.

Title: (1) Survey of Ocean Freight Revenues and Expenses of United States Carriers (BE–30). (2) Survey of U.S. Airline Operators' Foreign Revenues and Expenses (BE–37).

Form Number(s): BE–30/BE–37.

Agency Approval Number: 0608–0011.

Type of Request: Extension of a currently approved collection.

Burden: 780 hours/368 hours.

Number of Respondents: 39/23.

Avg Hours Per Response: 5 hours/4 hours.

Needs and Uses: The Bureau of Economic Analysis is responsible for the computation and publication of the U.S. balance of payments accounts. The information collected in these surveys are an integral part of the ''transportation'' portion of the U.S. balance of payments accounts. The balance of payments accounts, which are published quarterly in the Bureau's monthly publication, the *Survey of Current Business*, are one of the major statistical products of BEA. The accounts provide a statistical summary of U.S. international transactions. They are used by government and private organizations for national and international policy formulation, and analytical studies. Without the information collected in these surveys, an integral component of the transportation account would be omitted. No other Government agency collects comprehensive quarterly data on U.S. ocean carriers' freight revenues and expenses or U.S. airline operators' foreign revenues and expenses.

These surveys request information from U.S. ocean and air carriers engaged in the international transportation of goods and/or passengers. Information is collected on a quarterly basis from U.S. ocean and air carriers with total annual covered revenues and total annual covered expenses, each over $500,000. U.S. ocean and air carriers with total annual covered revenues and expenses below $500,000 are exempt from reporting.

Frequency: Quarterly.

Respondent's Obligation: Mandatory.

Legal Authority: The International Investment and Trade in Services Act, 22 U.S.C. 3101–3108.

OMB Desk Officer: Paul Bugg, (202) 395–3093.

Copies of the above extension of a currently approved collection can be obtained by calling or writing Madeleine Clayton, DOC Forms Clearance Officer, (202) 482–3129, Department of Commerce, room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations in response to this extension of a currently approved collection should be sent within 30 days of publication of this notice to Paul Bugg, OMB Desk Officer, room 10102, New Executive Office Building, Washington, DC 20503.

Dated: December 29, 2000.

Madeleine Clayton,

DOC Forms Clearance Officer, Office of Chief Information Officer.

[FR Doc. 01–279 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–06–U

DEPARTMENT OF COMMERCE

Submission For OMB Review; Comment Request

DOC has submitted to the Office of Management and Budget (OMB) for clearance, the following proposal for an extension of a currently approved collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

*Agency:*Bureau of Economic Analysis.

Title: Survey of Foreign Ocean Carriers' Expenses in the United States.

Form Number(s): BE–29.

Agency Approval Number: 0608–0012.

Type of Request: Extension of a currently approved collection.

Burden: 640 hours.

Number of Respondents: 160.

Avg Hours Per Response: 4 hours.

Needs and Uses: The Bureau of Economic Analysis is responsible for the computation and publication of the U.S. balance of payments accounts. The information collected in this survey is an integral part of the ''transportation'' portion of the U.S. balance of payments accounts. The balance of payments accounts, which are published quarterly in the Bureau's monthly publication, the Survey of Current Business, are one of the major statistical products of BEA. The accounts provide a statistical summary of U.S. international transactions. They are used by government and private organizations for national and international policy formulation, and analytical studies. Without the information collected in this survey, an integral component of the transportation account would be omitted. No other Government agency collects comprehensive annual data on foreign ocean carriers' expenses in the United States.

The survey requests information from U.S. agents of foreign ocean carriers. Information is collected on an annual basis from U.S. agents that handle 40 or more port calls by foreign vessels or have annual total covered expenses above $250,000. U.S. agents with less than 40 port calls or with annual total covered expenses below $250,000 are exempt from reporting.

Affected Public: U.S. agents of foreign ocean carriers.

Frequency: Annually.

Respondent's Obligation: Mandatory.

Legal Authority: The International Investment and Trade in Services Act, 22 U.S.C. 3101–3108.

OMB Desk Officer: Paul Bugg, (202) 395–3093.

Copies of the above extension of a currently approved collection can be obtained by calling or writing Madeleine Clayton, DOC Forms Clearance Officer, (202) 482–3129, Department of Commerce, room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations in response to this extension of a currently approved collection should be sent within 30 days of publication of this notice to Paul Bugg, OMB Desk Officer, room 10102, New Executive Office Building, Washington, DC 20503.

Dated: December 29, 2000.

Madeleine Clayton,

DOC Forms Clearance Officer, Office of Chief Information Officer.

[FR Doc. 01–280 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–06–U

DEPARTMENT OF COMMERCE

Submission For OMB Review; Comment Request

DOC has submitted to the Office of Management and Budget (OMB) for clearance, the following proposal for an extension of a currently approved collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of Economic Analysis.

Title: Survey of Foreign Airline Operators' Revenues and Expenses in the United States.

Form Number(s): BE–36.

Agency Approval Number: 0608–0013.

Type of Request: Extension of a currently approved collection.

Burden: 360 hours.

Number of Respondents: 72.

Avg Hours Per Response: 5 hours.

Needs and Uses: The Bureau of Economic Analysis is responsible for the computation and publication of the U.S. balance of payments accounts. The information collected in this survey is an integral part of the ''transportation'' portion of the U.S. balance of payments accounts. The balance of payments accounts, which are published quarterly in the Bureau's monthly publication, the *Survey of Current Business,* are one of the major statistical products of BEA. The accounts provide a statistical summary of U.S. international

transactions. They are used by government and private organizations for national and international policy formulation, and analytical studies. Without the information collected in this survey, an integral component of the transportation account would be omitted. No other Government agency collects comprehensive annual data on foreign airline operators' revenues and expenses in the United States.

The survey requests information from foreign air carriers operating in the United States. Information is collected on an annual basis from foreign air carriers with total annual covered revenues and total annual covered expenses incurred in the U.S., each over $500,000. Foreign air carriers with total annual covered revenues and expenses below $500,000 are exempt from reporting.

Frequency: Annually.

Respondent's Obligation: Mandatory.

Legal Authority: The International Investment and Trade in Services Act, 22 U.S.C. 3101–3108.

OMB Desk Officer: Paul Bugg, (202) 395–3093.

Copies of the above extension of a currently approved collection can be obtained by calling or writing Madeleine Clayton, DOC Forms Clearance Officer, (202) 482–3129, Department of Commerce, room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations in response to this extension of a currently approved collection should be sent within 30 days of publication of this notice to Paul Bugg, OMB Desk Officer, room 10102, New Executive Office Building, Washington, DC 20503.

Dated: December 29, 2000.

Madeleine Clayton,

DOC Forms Clearance Officer, Office of Chief Information Officer.

[FR Doc. 01–281 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–06–U

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–802]

Gray Portland Cement and Clinker From Mexico; Notice of Extension of Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limits for final results of antidumping duty administrative review.

SUMMARY: The Department of Commerce is extending the time limit for the final results of the antidumping duty administrative review of the antidumping duty order on gray portland cement and clinker from Mexico. The review covers one manufacturer/exporter, CEMEX, S.A. de C.V. (CEMEX), and its affiliate, Cementos de Chihuahua, S.A. de C.V. (CDC). The period of review is August 1, 1998, through July 31, 1999.

EFFECTIVE DATE: January 5, 2001.

FOR FURTHER INFORMATION CONTACT: David Dirstine or Minoo Hatten, AD/CVD Enforcement Group I, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–4033 and (202) 482–1690, respectively.

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department of Commerce's (the Department's) regulations are to 19 CFR part 351 (1999).

Extension of Time Limits for Final Results

The Department published the preliminary results of this administrative review on September 7, 2000 (64 FR 54220). The deadline for completing the final results of review is January 5, 2000. Under section 751(a)(3)(A) of the Act, the Department may extend the deadline for completion of an administrative review if it determines that it is not practicable to complete the review within the statutory time limit. Due to the complexity of the issues in this case, such as whether certain sales are outside the ordinary course of trade and how difference-in-merchandise adjustments are calculated, and due to administrative constraints, the Department determines that it is not practicable to complete the final results of this review within the statutory time limits mandated by section 751(a)(3)(A) of the Act. Therefore, the Department is extending the time limit for the final results of this review to February 5, 2000.

Dated: December 27, 2000.

Richard W. Moreland,

Deputy Assistant Secretary for AD/CVD Enforcement I.

[FR Doc. 01–275 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–822]

Certain Helical Spring Lock Washers From the People's Republic of China; Final Results of Antidumping Duty Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of antidumping duty review.

SUMMARY: On September 8, 2000, the Department of Commerce published the preliminary results of the administrative review of the antidumping duty order on certain helical spring lock washers from the People's Republic of China. This review covers one manufacturer/exporter, Zhejiang Wanxin Group Co. Ltd., the predecessor firm to Hang Zhou Spring Washer Co. (collectively Hangzhou), and the period is October 1, 1998, through September 30, 1999. We gave interested parties an opportunity to comment on the preliminary results of review but received no comments. As in the preliminary results, we have found that the sales of certain helical spring lock washers were made below normal value.

EFFECTIVE DATE: January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Sally Hastings or Craig Matney, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–3464 or (202) 482–1778, respectively.

SUPPLEMENTARY INFORMATION:

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (''the Act''), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department of Commerce's (''the Department'') regulations are to 19 CFR part 351 (1999).

Background

On September 8, 2000, the Department published in the **Federal Register** the preliminary results of its administrative review of helical spring lock washers (''HSLWs'') from the PRC (*Certain Helical Spring Lock Washers from the People's Republic of China; Preliminary Results of Antidumping Duty Administrative Review*), 65 FR 54493 (September 8, 2000) (''*Preliminary Results*''). We issued a second supplemental questionnaire to Hangzhou on September 7, 2000, requesting plater-specific information and a revised factors of production database. Hangzhou submitted its response on September 21, 2000. We invited parties to comment on our preliminary results of review, but we received no comments. The Department has now completed the antidumping duty administrative review in accordance with section 751 of the Act.

Scope of Review

The products covered by this review are HSLWs of carbon steel, of carbon alloy steel, or of stainless steel, heat-treated or non-heat-treated, plated or non-plated, with ends that are off-line. HSLWs are designed to: (1) Function as a spring to compensate for developed looseness between the component parts of a fastened assembly; (2) distribute the load over a larger area for screws or bolts; and, (3) provide a hardened bearing surface. The scope does not include internal or external tooth washers, nor does it include spring lock washers made of other metals, such as copper.

HSLWs subject to this review are currently classifiable under subheading 7318.21.0030 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of this proceeding is dispositive.

Verification

Pursuant to section 782(i) of the Act, we verified sales and factors of production information provided by Hangzhou in Xiaoshan, PRC, using standard verification procedures, including the examination of relevant sales, accounting and production records, as well as original source documents provided by the respondents. Our verification results are outlined in the public version of the verification report, dated August 14, 2000, and located in the public file in the Central Records Unit, room B–099 of the Department's main building.

Comparisons

We calculated export price and normal value based on the same methodology used in the *Preliminary Results* and analyzed the additional plating information submitted by respondent.

Final Results of the Review

Respondent Hangzhou submitted the requested additional plater-specific information and revised factors of production database on September 21, 2000. We have incorporated this new information in our analysis for purposes of these final results (*See* Calculation Memorandum from Craig Matney to file dated December 27, 2000). The weighted-average dumping margin for the period October 1, 1998 through September 30, 1999, is as follows:

Manufacturer/exporter	Time period	Margin (percent)
Hang Zhou Spring Washer Co. Ltd/Zhejiang Wanxin Group Co., Ltd. (ZWG)	10/01/98–09/30/99	2.76

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. The Department will issue appraisement instructions directly to the Customs Service.

Furthermore, the following deposit rates will be effective upon publication of these final results for all shipments of HSLWs from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(1) of the Act: (1) For Hangzhou, which has a separate rate, the cash deposit rate will be the company-specific rate established in these final results of review; (2) for all other PRC exporters, the cash deposit rate will be the PRC rate, 128.63 percent, which is the All Other PRC Manufacturers, Producers and Exporters rate from the *Final Determination of Sales at Less Than Fair Value: Certain Helical Spring Lock Washers from the PRC,* 58 FR 48833 (September 20, 1993); and, (3) for non-PRC exporters of subject merchandise from the PRC, the cash deposit rate will be the rate applicable to the PRC supplier of that exporter. These deposit rates shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: December 27, 2000.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 01–276 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–25–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–818, A–428–828, A–421–808, A–412–820]

Notice of Initiation of Antidumping Duty Investigations: Low Enriched Uranium From France, Germany, the Netherlands, and the United Kingdom

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Initiation of Antidumping Duty Investigations.

EFFECTIVE DATE: January 5, 2001.

FOR FURTHER INFORMATION CONTACT: James Terpstra (Germany, the Netherlands, the United Kingdom) at (202) 482–3965, and Gabriel Adler (France) at (202) 482–3813, Office 6 and 5, respectively, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, Room 1870, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

Initiation of Investigations

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are references to the provisions codified at 19 CFR Part 351 (2000).

The Petitions

On December 7, 2000, the Department of Commerce (the Department) received petitions filed in proper form by USEC Inc., and its wholly owned subsidiary, United States Enrichment Corporation. On December 26, 2000, the Department received a letter from USEC amending the petitions to add the Paper, Allied-Industrial, Chemical and Energy Workers International Union, AFL–CIO, CLC, and Local 5–550 and Local 5–689 (collectively PACE) to the petitions as an interested party pursuant to section 771(9)(D) of the Act. In addition, PACE filed its own letter on December 26, 2000, expressing support for and joining the petitions. The Department received from the petitioners information supplementing the petitions throughout the 20-day initiation period.

In accordance with section 732(b) of the Act, the petitioners allege that imports of low enriched uranium from France, Germany, the Netherlands, and the United Kingdom are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act, and that such imports are materially injuring an industry in the United States.

The Department finds that the petitioners filed these petitions on behalf of the domestic industry because they are an interested party as defined in sections 771(9)(C) and (D) of the Act and have demonstrated sufficient industry support with respect to each of the antidumping investigations that they are requesting the Department to initiate (*see* the *Determination of Industry Support for the Petitions* section below).

Scope of Investigations

For purposes of these investigations, the product covered is low enriched uranium (LEU). LEU is enriched uranium hexafluoride (UF_6) with a U^{235} product assay of less than 20 percent that has not been converted into another chemical form, such as UO_2, or fabricated into nuclear fuel assemblies, regardless of the means by which the LEU is produced (including LEU produced through the down-blending of highly enriched uranium).

Certain merchandise is outside the scope of these investigations. Specifically, these investigations do not cover enriched uranium hexafluoride with a U^{235} assay of 20 percent or greater, also known as highly enriched uranium. In addition, fabricated LEU is not covered by the scope of these investigations. For purposes of these investigations, fabricated uranium is defined as enriched uranium dioxide (UO_2), whether or not contained in nuclear fuel rods or assemblies. Natural uranium concentrates (U_3O_8) with a U^{235} concentration of no greater than 0.711 percent and natural uranium concentrates converted into uranium hexafluoride with a U^{235} concentration of no greater than 0.711 percent are not covered by the scope of these investigations.

The merchandise subject to these investigations is classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 2844.20.0020. Subject merchandise may also enter under 2844.20.0030, 2844.20.0050, and 2844.40.00. Although the HTSUS subheadings are provided for convenience and U.S. Customs purposes, the written description of the merchandise under investigation is dispositive.

During our review of the petitions, we discussed the scope with the petitioners to ensure that it accurately reflects the product for which the domestic industry is seeking relief. Moreover, as discussed in the preamble to the Department's regulations (62 FR 27323), we are setting aside a period for parties to raise issues regarding product coverage. The Department encourages all parties to submit such comments by January 17, 2001. Comments should be addressed to Import Administration's Central Records Unit at Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230. The period for scope comments is intended to provide the Department with ample opportunity to consider all comments and consult with parties prior to the issuance of the preliminary determinations.

Determination of Industry Support for the Petitions

Section 771(4)(A) of the Act defines the ''industry'' as the producers of a domestic like product. Thus, to determine whether the petitions have the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes the domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to separate and distinct authority. In addition, the Department's determination is subject to greater limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to the law.[1]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation,'' *i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition. Moreover, the petitioners do not offer a definition of domestic like product

[1] *See Algoma Steel Corp. Ltd.,* v. *United States*, 688 F. Supp. 639, 642–44 (CIT 1988); *High Information Content Flat Panel Displays and Display Glass Therefore from Japan: Final Determination; Rescission of Investigation and Partial Dismissal of Petition*, 56 FR 32376, 32380–81 (July 16, 1991).

distinct from the scope of these investigations.

The domestic like product referred to in the petitions is the single domestic like product defined in the *Scope of Investigations* section, above. The Department has no basis on the record to find the petitioners' definition of the domestic like product to be inaccurate. The Department, therefore, has adopted the domestic like product definition set forth in the petitions.

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (1) At least 25 percent of the total production of the domestic like product; and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Finally, section 732(c)(4)(D) of the Act provides that if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the administering agency shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition as required by subparagraph (A), or (ii) determine industry support using a statistically valid sampling method.

In order to estimate production for the domestic industry as defined for purposes of this case, the Department has relied upon not only the petitions and amendments thereto, but also upon ''other information'' it obtained through research and which is attached to the Initiation Checklist (*See Import Administration AD Investigation Initiation Checklist* (*Initiation Checklist*) and *Industry Support Memorandum* from Melissa G. Skinner to Holly A. Kuga dated December 27, 2000 (*Industry Support Memorandum*). Based on information from these sources, the Department determined, pursuant to section 732(c)(4)(D), that there is support for the petition as required by subparagraph (A). Specifically, the Department made the following determinations. For France, Germany, the Netherlands, and the United Kingdom, the petitioners established industry support representing over 50 percent of total production of the domestic like product. Therefore, the domestic producers or workers who support the petitions account for at least 25 percent of the total production of the domestic like product, and the requirements of section 732(c)(4)(A)(i) are met.

On December 19, 2000, the Ad Hoc Utilities Group (the Utilities Group) (Arizona Public Service Co.; Carolina Power & Light Co.; Commonwealth Edison Co.; Consumers Energy; Dominion Generation, Duke Energy Corp.; DTE Energy; Entergy Services, Inc.; First Energy Nuclear Operating Co.; Nuclear Management Co.; PSEG Nuclear LLC; Southern Nuclear Operating Co.; Union Electric Company (d/b/a AmerenUE); and Wolf Creek Nuclear Operating Corp.) filed a letter asserting that the Utilities Group members are domestic producers of LEU and that the petitioners lack industry support, because USEC produces less than 25 percent of domestic LEU. On December 20, 2000, Eurodif/Cogema and Urenco filed a submission claiming that the petitioners did not have standing in order to file the petitions. Both the Utilities Group and Eurodif/Cogema and Urenco argue that the petitioners are in the business of providing a service (*i.e.,* the enrichment of uranium), rather than manufacturing a product, and the antidumping law does not apply to services. In addition, they argue that the vast majority of the petitioners' production of enriched uranium is performed under a tolling arrangement, whereby the utilities provide the petitioners with converted uranium, and retain title to the input while the petitioners enrich it. The utilities and foreign respondents argue that the utilities are the producers for these transactions.

On December 21, 2000, the petitioners submitted a letter to rebut the Utilities Group's comments on industry support. The petitioners argue that the tolling regulation has no relevance in determining who is a U.S. producer or manufacturer of the domestic like product for standing purposes. In addition, the petitioners argue that the Utilities Group provided no factual support for its claim that its members are producers of LEU, and that it is not an interested party.

On December 22, 2000, the petitioners submitted additional comments with regard to the above comments made by the Utilities Group and Eurodif/Cogema and Urenco.

As explained in *The Petitions* section above, PACE filed a letter on December 26, 2000, joining the petitions.

On December 26, 2000, Eurodif/Cogema and Urenco submitted additional comments regarding their December 20, 2000, submission on industry support.

Based on our analysis of the comments received from the Utilities Group, Eurodif/Cogema, Urenco, and the petitioners, the Department determined that the utilities were not part of the domestic industry producing LEU. *See Industry Support Memorandum,* where we found that the utility companies do not engage in any manufacturing type of activities with respect to the production of LEU.

Because the Department determined that the utilities were not part of the domestic industry, the Department received no opposition from the LEU industry to the petitions. Therefore, the domestic producers or workers who support the petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for or opposition to the petitions. Thus, the requirements of section 732(c)(4)(A)(ii) are also met.

Accordingly, the Department determines that the petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act. *See* the *Initiation Checklist.*

Export Price and Normal Value

The following are descriptions of the allegations of sales at less than fair value upon which the Department based its decision to initiate these investigations. The sources of data for the deductions and adjustments relating to home market price, U.S. price, and constructed value (CV) are detailed in the *Initiation Checklist.* Where the petitioners relied on data reported by a market researcher, the petitioners also supplied affidavits from company officials regarding this data. In addition, we spoke to the market researcher to establish that person's credentials and to confirm the validity of the information being provided. For purposes of these initiations, we have not relied on specific margins where the petitioners' sources were unable to firmly establish the identity of the producer. *See Initiation Checklist* and Memorandum to the File, *Telephone Conversation with Source of Market Research used in Antidumping Petitions to Support Certain Factual Information*, dated December 27, 2000. Should the need arise to use any of this information as facts available under section 776 of the Act in our preliminary or final determinations, we may re-examine the information and revise the margin calculations, if appropriate.

The petitioners based their allegations on a 33-month period because of the long-term contracts that are characteristic of the uranium industry. *See* the *Initiation Checklist.* The Department will consider the appropriate period of information

collection in this case after initiation. As discussed below, the following margins are based on constructed value: France 18.28 to 53.30 percent, Germany 19.44 to 29.52 percent, the Netherlands 10.76 to 29.22 percent, and the United Kingdom 15.57 to 23.25 percent.

France

Export Price

The petitioners based prices of Eurodif's/Cogema's sales to U.S. utilities on information obtained from market research. Although the petitioners stated that Eurodif/Cogema makes sales to the U.S. utilities through its affiliated company in the United States, making U.S. prices constructed export prices (CEP), the petitioners made no deductions to the CEP for selling expenses.

Normal Value

With respect to normal value (NV), the petitioners stated that they were not aware of any sales made by Eurodif/Cogema in France since January 1998. Instead, the petitioners based NV on a Eurodif/Cogema sale to Japan, its largest third country market as reported in an affidavit from a company official with the petitioners. The petitioners did not make any adjustments to the starting price.

Although the petitioners provided information on NV, they also provided information demonstrating reasonable grounds to believe or suspect that sales of LEU in the third country market were made at prices below the fully absorbed COP, within the meaning of section 773(b) of the Act, and requested that the Department conduct a country-wide sales-below-cost investigation.

Pursuant to section 773(b)(3) of the Act, COP consists of the cost of manufacturing (COM), sales, general, and administrative (SG&A) expenses, and packing. The petitioners calculated Eurodif's COM including raw material cost, energy, labor, variable and fixed costs. G&A expenses were derived from the Eurodif financial statements while financial expenses were calculated from the consolidated parent company financial statements. *See* the *Initiation of Cost Investigations* section below.

Based upon the comparison of the prices of the foreign like product in the comparison market to the calculated COP of the product, we find reasonable grounds to believe or suspect that sales of the foreign like product were made below the COP, within the meaning of section 773(b)(2)(A)(i) of the Act. Accordingly, the Department is initiating a country-wide cost investigation with respect to sales in Japan. In the event that the Department determines that Japan is the appropriate market upon which to base normal value, we will conduct a COP investigation. Because the comparison market prices petitioners used for LEU sales are below the COP, the petitioners based NV on CV. The petitioners calculated CV incorporating the same costs used for the COP. The petitioners included in CV an amount for profit which was based on the profit of Eurodif from its financial statements.

Based upon the comparison of EP to CV, the petitioners calculated estimated dumping margins ranging from 18.28 to 53.30 percent.

Germany

Export Price

For Germany, the petitioners based EP on prices from reports of Urenco's U.S. sales of LEU published by the petitioners' market researcher. The petitioners stated that Urenco makes sales to U.S. utilities through its affiliated sales agent in the United States. Thus, the petitioners contend that the U.S. sales should be treated as CEP sales in the investigation. However, for purposes of the petition, the petitioners stated that they did not make any adjustments to the starting price.

Normal Value

With respect to NV, the petitioners based Urenco's home market prices for LEU on an affidavit from a company official with the petitioners. The petitioners stated that they did not make any adjustments to the starting price.

Although the petitioners provided information on home market prices, they also provided information demonstrating reasonable grounds to believe or suspect that sales of LEU in the home market were made at prices below the fully absorbed COP, within the meaning of section 773(b) of the Act, and requested that the Department conduct a country-wide sales-below-cost investigation.

Pursuant to section 773(b)(3) of the Act, COP consists of the COM, SG&A expenses, and packing. The petitioners calculated Urenco Deutschland's COM including raw material cost, energy, labor, variable and fixed costs. G&A expenses were derived from the company's financial statements while financial expenses were calculated from the consolidated parent company financial statements. *See* the *Initiation of Cost Investigations* section below.

Based upon the comparison of the prices of the foreign like product in the home market to the calculated COP of the product, we find reasonable grounds to believe or suspect that sales of the foreign like product were made below the COP, within the meaning of section 773(b)(2)(A)(i) of the Act. Accordingly, the Department is initiating a country-wide cost investigation. Because the home market price is below the COP, the petitioners based NV on CV. The petitioners calculated CV incorporating the same costs used for the COP. The petitioners included in CV an amount for profit which was based on the profit of the Urenco Deutschland's financial statements.

Based upon the comparison of EP to CV, the petitioners calculated estimated dumping margins ranging from 19.44 to 29.52 percent.

The Netherlands

Export Price

For the Netherlands, the petitioners based EP on prices from reports of Urenco's U.S. sales of LEU published by their market researcher. The petitioners stated that Urenco makes sales to U.S. utilities through its affiliated sales agent in the United States. Thus, the petitioners contend that the U.S. sales should be treated as CEP sales in the investigation. However, for purposes of the petition, the petitioners stated that they did not make adjustments to the starting price.

Normal Value

With respect to NV, the petitioners explained that they were not aware of any sales made by Urenco in the Netherlands during the 33-month period. Instead, the petitioners based their NV on a Urenco sale to the Republic of Korea, its largest third country market as reported in an affidavit from a company official with the petitioners. The petitioners stated that they did not make any adjustments to the starting price. Although the petitioners provided information on NV, they also provided information demonstrating reasonable grounds to believe or suspect that sales of LEU in the third country market were made at prices below the fully absorbed COP, within the meaning of section 773(b) of the Act, and requested that the Department conduct a country-wide sales-below-cost investigation.

Pursuant to section 773(b)(3) of the Act, COP consists of the COM, SG&A expenses, and packing. The petitioners calculated Urenco Nederland's COM including raw materials, energy, labor variable and fixed costs. The petitioners claimed to be unable to obtain a copy of Urenco Nederland's 1998 or 1999 financial statement. As a surrogate, all costs were derived from the Urenco

Deutschland's financial statements, except depreciation and financial expenses. *See* the *Initiation of Cost Investigations section below.*

Based upon the comparison of the comparison market prices of the foreign like product to the calculated COP of the product, we find reasonable grounds to believe or suspect that sales of the foreign like product were made below the COP, within the meaning of section 773(b)(2)(A)(i) of the Act. Accordingly, the Department is initiating a country-wide cost investigation with respect to Korea. In the event that the Department determines that Korea is the appropriate market upon which to base normal value, we will conduct a COP investigation. Because the NV petitioners used for LEU sales is below the COP, the petitioners based NV on CV. The petitioners calculated CV incorporating the same costs used for the COP. The petitioners included in CV an amount for profit which was based on the profit of the Urenco Deutschland's financial statements.

Based upon the comparison of EP to CV, the petitioners calculated estimated dumping margins ranging from 10.76 to 29.22 percent.

The United Kingdom

Export Price

For the United Kingdom, the petitioners based EP on prices from reports of Urenco's U.S. sales of LEU published by their market researcher. The petitioners stated that Urenco makes sales to U.S. utilities through its affiliated sales agent in the United States. Thus, the petitioners contend that the U.S. sales should be treated as CEP sales in the investigation. However, for purposes of the petition, the petitioners stated that they did not make any adjustments to the starting price.

Normal Value

With respect to NV, the petitioners based Urenco's home market price for LEU on an affidavit from a company official with the petitioners. The petitioners stated that they did not make any adjustments to the starting price.

Although the petitioners provided information on home market prices, they also provided information demonstrating reasonable grounds to believe or suspect that sales of LEU in the home market were made at prices below the fully absorbed COP, within the meaning of section 773(b) of the Act, and requested that the Department conduct a country-wide sales-below-cost investigation.

Pursuant to section 773(b)(3) of the Act, COP consists of the COM, SG&A expenses, and packing. The petitioners calculated Urenco (Capenhurst), Ltd.'s COM including raw materials, energy, labor variable and fixed costs. G&A expenses were derived from the Urenco Ltd.'s financial statements while financial expenses were calculated from the consolidated parent company financial statements. *See* the *Initiation of Cost Investigations* section below.

Based upon the comparison of the prices of the foreign like product in the home market to the calculated COP of the product, we find reasonable grounds to believe or suspect that sales of the foreign like product were made below the COP, within the meaning of section 773(b)(2)(A)(i) of the Act. Accordingly, the Department is initiating a country-wide cost investigation. Because the home market price is below the COP, the petitioners based NV on CV. The petitioners calculated CV incorporating the same costs used for the COP. The petitioners included in CV an amount for profit which was based on the profit of the Urenco Ltd.'s financial statements.

Based upon the comparison of EP to CV, the petitioners calculated estimated dumping margins ranging from 15.57 to 23.25 percent.

Initiation of Cost Investigations

As noted above, pursuant to section 773(b) of the Act, the petitioners provided information demonstrating reasonable grounds to believe or suspect that sales in the home markets, or respective third country market of France, Germany, the Netherlands, and the United Kingdom were made at prices below the fully absorbed COP. The petitioners requested that the Department conduct country-wide sales-below-cost investigations in connection with the requested antidumping investigations for these countries. The Statement of Administrative Action, accompanying the URAA states that an allegation of sales-below-cost need not be specific to individual exporters or producers. SAA, H. Doc. 103–316, Vol. 1, 103d Cong., 2d Session, at 833(1994). The SAA, at 833, states that ''Commerce will consider allegations of below-cost sales in the aggregate for a foreign country, just as Commerce currently considers allegations of sales at less than fair value on a country-wide basis for purposes of initiating an antidumping investigation.''

Further, the SAA provides that ''new section 773(b)(2)(A) retains the current requirement that Commerce have 'reasonable grounds to believe or suspect' that below cost sales have occurred before initiating such an investigation. 'Reasonable grounds' * * * exist when an interested party provides specific factual information on costs and prices, observed or constructed, indicating that sales in the foreign market in question are at below-cost prices.'' *Id.* Based upon the comparison of the adjusted prices from the petitions for the representative foreign like products to their COPs, we find the existence of ''reasonable grounds to believe or suspect'' that sales of these foreign like products in the relevant markets for France, Germany, the Netherlands, and the United Kingdom were made at prices below their respective COPs within the meaning of section 773(b)(2)(A)(i) of the Act. Accordingly, the Department is initiating the requested country-wide cost investigations with respect to each of the four countries.

Fair Value Comparisons

Based on the data provided by the petitioners, there is reason to believe that imports of LEU from France, Germany, the Netherlands, and the United Kingdom are being, or are likely to be, sold at less than fair value.

Allegations and Evidence of Material Injury and Causation

The petitions allege that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the individual and cumulated imports of the subject merchandise sold at less than NV. The petitioners contend that the industry's injured condition is evident in the declining trends in net operating profits, net sales volumes, profit-to-sales ratios, and capacity utilization. The allegations of injury and causation are supported by relevant evidence including U.S. Customs import data, lost sales, and pricing information. We have assessed the allegations and supporting evidence regarding material injury and causation, and have determined that these allegations are properly supported by accurate and adequate evidence and meet the statutory requirements for initiation (*see Initiation Checklist* at Attachment II Re: Material Injury).

Initiation of Antidumping Investigations

Based upon our examination of the petitions on LEU, and the petitioners' responses to our supplemental questionnaire clarifying the petitions, as well as our conversation with the market researcher who provided information concerning various aspects of the petitions, we have found that the petitions meet the requirements of section 732 of the Act. Therefore, we are

initiating antidumping duty investigations to determine whether imports of LEU from France, Germany, the Netherlands, and the United Kingdom are being, or are likely to be, sold in the United States at less than fair value. Unless extended, we will make our preliminary determinations no later than 140 days after the date of these initiations.

Distribution of Copies of the Petitions

In accordance with section 732(b)(3)(A) of the Act, a copy of the public version of each petition has been provided to the representatives of the governments of France, Germany, the Netherlands, and the United Kingdom. We will attempt to provide a copy of the public version of each petition to each exporter named in the petition, as appropriate.

International Trade Commission Notification

We have notified the ITC of our initiations, as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will determine, no later than January 22, 2001, whether there is a reasonable indication that imports of LEU from France, Germany, the Netherlands, and the United Kingdom are causing material injury, or threatening to cause material injury, to a U.S. industry. A negative ITC determination for any country will result in the investigation being terminated with respect to that country; otherwise, these investigations will proceed according to statutory and regulatory time limits.

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: December 27, 2000.

Holly A. Kuga,

Acting Assistant Secretary for Import Administration.

[FR Doc. 01–274 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–504]

Notice of Extension of Time Limit for Final Results of Antidumping Administrative Review: Petroleum Wax Candles from the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Matthew Renkey or Abdelali Elouaradia, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2312 and (202) 482–1374, respectively.

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act) are to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department's regulations are to 19 CFR part 351 (1999).

Background

On August 13, 1999, in accordance with 19 CFR 351.213(b), counsel for three PRC companies requested that we conduct an administrative review. These three companies were Shanghai Gift and Travel Products Import and Export Corporation, Liaoning Native Product Import and Export Corporation, and Tianjin Native Produce Import and Export Group Corporation, Ltd. On August 31, 1999, the National Candle Association (petitioner), requested that we conduct an administrative review of twenty-two specific producers/exporters. On October 1, 1999, the Department published its initiation of this administrative review for the period August 1, 1998 through July 31, 1999 (64 FR 53318). On September 7, 2000, the Department published the preliminary results of this review (65 FR 54224).

Extension of Time Limits for Final Results

Due to the complexities involved with this particular case, including whether a respondent is eligible for a separate rate and the choice of adverse facts available, we find that it is not practicable to make a final determination by the current deadline of January 5, 2001. Therefore, in accordance with section 751(a)(3)(A) of the Act and section 351.213(h)(2) of the Department's regulations, the Department is extending the time period for issuing the final results of this review until no later than March 6, 2001.

Dated: December 29, 2000.

Joseph A. Spetrini,

Deputy Assistant Secretary, AD/CVD Enforcement Group III.

[FR Doc. 01–383 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–001]

Sorbitol From France; Time Limits

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limit for preliminary results of antidumping duty administrative review.

SUMMARY: The Department of Commerce (the Department) is extending the time limit for the preliminary results of the 1999–2000 administrative review of the antidumping duty order on sorbitol from France. This review covers one exporter of the subject merchandise to the United States, Amylum France and Amylum SPI Europe (collectively, Amylum). The period of review is April 1, 1999 through March 31, 2000.

EFFECTIVE DATE: January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Fred Baker at (202) 482–2924 or Robert James at (202) 482–0649, Antidumping and Countervailing Duty Enforcement Group III, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION: The Department initiated this administrative review on June 2, 2000 (65 FR 35320). Under section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Tariff Act), the Department may extend the deadline for completion of an administrative review if it determines that it is not practicable to complete the review within the statutory time limit of 365 days. Because of the complexity of researching whether or not Amylum entries during the period of review (POR), and the need to allow parties the opportunity to comment on the results of our research prior to issuing preliminary results of review, we are extending the time limit for completion of the preliminary results until April 30, 2001. *See* Memorandum from Richard Weible to Joseph Spetrini, titled, ''Extension of Time Limit for the April 1999 through March 2000 Administrative Review,'' dated the same date as the publication of this notice, on file in room B–099 of the main Commerce building. The deadline for the final results will continue to be 120 days after the publication of the preliminary results.

This extension is in accordance with section 751(a)(3)(A) of the Tariff Act and section 351.213(h)(2) of the Department's regulations.

Dated: December 29, 2000.

Joseph A. Spetrini,

Deputy Assistant Secretary, Enforcement Group III.

[FR Doc. 01–384 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–834]

Notice of Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review: Stainless Steel Sheet and Strip in Coils From Korea

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limit for the preliminary results of antidumping duty administrative review.

SUMMARY: The Department of Commerce (''Department'') is extending the time limit for the preliminary results of the review of stainless steel sheet and strip in coils from the Republic of Korea. This review covers the period January 4, 1999 through June 30, 2000.

EFFECTIVE DATE: January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Laurel LaCivita, AD/CVD Enforcement Group III, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–4243.

The Applicable Statute

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (''the Act'') by the Uruguay Round Agreements Act (''URAA'').

Extension of Time Limit for Preliminary Results

Because of the complex issues enumerated in the Memorandum from Edward C. Yang to Joseph A. Spetrini, *Extension of Time Limit for the Preliminary Results of Administrative Review of Certain Stainless Steel Sheet and Strip in Coils from Korea,* on file in the Central Records Unit (CRU) of the Main Commerce Building, Room B–099, we find that it is not practicable to complete this review by the scheduled deadline of April 2, 2001. Therefore, in accordance with section 751(a)(3)(A) of the Act, the Department is extending the time period for issuing the preliminary results of review by 90 days until July 2, 2001.

Dated: December 29, 2000.

Joseph A. Spetrini,

Deputy Assistant Secretary, AD/CVD Enforcement Group III.

[FR Doc. 01–386 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

(C–427–819, C–428–829, C–421–809, C–412–821]

Notice of Initiation of Countervailing Duty Investigations: Low Enriched Uranium From France, Germany, The Netherlands, and the United Kingdom

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Initiation of countervailing duty investigations.

EFFECTIVE DATE: January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Michael Grossman (France) at (202) 482–3146; Robert Copyak (Germany) at (202) 482–2209; Stephanie Moore (The Netherlands) at (202) 482–3692; and Eric B. Greynolds (United Kingdom) at (202) 482–6071, Office 6, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, Room 1870, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

Initiation of Investigations

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are references to the provisions codified at 19 CFR Part 351 (2000).

The Petitions

On December 7, 2000, the Department of Commerce (the Department) received petitions filed in proper form by USEC Inc., and its wholly owned subsidiary, United States Enrichment Corporation. On December 26, 2000, the Department received a letter from USEC amending the petitions to add the Paper, Allied-Industrial, Chemical and Energy Workers International Union, AFL–CIO, CLC, and Local 5–550 and Local 5–689 (collectively PACE) to the petitions as an interested party pursuant to section 771(9)(D) of the Act. In addition, PACE filed its own letter on December 26, 2000, expressing support for and joining the petitions. The Department received from petitioners information supplementing the petitions throughout the 20-day initiation period.

In accordance with section 702(b) of the Act, petitioners allege manufacturers, producers, or exporters of low enriched uranium from France, Germany, the Netherlands, and the United Kingdom received countervailable subsidies within the meaning of section 701 of the Act.

The Department finds that petitioners filed these petitions on behalf of the domestic industry because they are an interested party as defined in sections 771(9)(C) and (D) of the Act and have demonstrated sufficient industry support with respect to each of the countervailing duty investigations that they are requesting the Department to initiate (*see* the *Determination of Industry Support for the Petitions* section below).

Scope of Investigations

For purposes of these investigations, the product covered is low enriched uranium (LEU). LEU is enriched uranium hexafluoride (UF_6) with a U^{235} product assay of less than 20 percent that has not been converted into another chemical form, such as UO_2, or fabricated into nuclear fuel assemblies, regardless of the means by which the LEU is produced (including LEU produced through the down-blending of highly enriched uranium).

Certain merchandise is outside the scope of these investigations. Specifically, these investigations do not cover enriched uranium hexafluoride with a U^{235} assay of 20 percent or greater, also known as highly enriched uranium. In addition, fabricated LEU is not covered by the scope of these investigations. For purposes of these investigations, fabricated uranium is defined as enriched uranium dioxide (UO_2), whether or not contained in nuclear fuel rods or assemblies. Natural uranium concentrates (U_3O_8) with a U^{235} concentration of no greater than 0.711 percent and natural uranium concentrates converted into uranium hexafluoride with a U^{235} concentration of no greater than 0.711 percent are not covered by the scope of these investigations.

The merchandise subject to these investigations is classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 2844.20.0020. Subject merchandise may

also enter under 2844.20.0030, 2844.20.0050, and 2844.40.00. Although the HTSUS subheadings are provided for convenience and U.S. Customs purposes, the written description of the merchandise under investigation is dispositive.

During our review of the petitions, we discussed the scope with the petitioners to ensure that it accurately reflects the product for which the domestic industry is seeking relief. Moreover, as discussed in the preamble to the Department's regulations (62 FR 27323), we are setting aside a period for parties to raise issues regarding product coverage. The Department encourages all parties to submit such comments by January 17, 2001. Comments should be addressed to Import Administration's Central Records Unit at Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. The period for scope comments is intended to provide the Department with ample opportunity to consider all comments and consult with parties prior to the issuance of the preliminary determinations.

Consultations

Pursuant to section 702(b)(4)(A)(ii) of the Act, the Department invited representatives of the relevant foreign governments as well as representatives from the Delegation of the European Commission for consultations with respect to the countervailing duty investigations. The Department held consultations with representatives of the governments of France, Germany, the Netherlands, the United Kingdom, and the Delegation of the European Commission on December 21, 2000. *See* the December 22, 2000, memoranda to the file regarding these consultations (public documents on file in the Central Records Unit of the Department of Commerce, Room B–099).

Determination of Industry Support for the Petitions

Section 771(4)(A) of the Act defines the ''industry'' as the producers of a domestic like product. Thus, to determine whether the petitions have the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes the domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to the law.[1]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation,'' *i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition. Moreover, the petitioners do not offer a definition of domestic like product distinct from the scope of these investigations.

The domestic like product referred to in the petitions is the single domestic like product defined in the *Scope of Investigations* section, above. The Department has no basis on the record to find the petitioners' definition of the domestic like product to be inaccurate. The Department, therefore, has adopted the domestic like product definition set forth in the petitions.

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (1) At least 25 percent of the total production of the domestic like product; and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Finally, section 702(c)(4)(D) of the Act provides that if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the administering agency shall: (i) poll the industry or rely on other information in order to determine if there is support for the petition as required by subparagraph (A), or (ii) determine industry support using a statistically valid sampling method.

[1] *See Algoma Steel Corp. Ltd.,* v. *United States,* 688 F. Supp. 639, 642–44 (CIT 1988); *High Information Content Flat Panel Displays and Display Glass Therefore from Japan: Final Determination: Rescission of Investigation and Partial Dismissal of Petition,* 56 FR 32376, 32380–81 (July 16, 1991).

In order to estimate production for the domestic industry as defined for purposes of this case, the Department has relied upon not only the petitions and amendments thereto, but also upon ''other information'' obtained through research, which is attached to the Initiation Checklist (*See Import Administration CVD Investigation Initiation Checklist (Initiation Checklist),* December 27, 2000, and the *Industry Support Memorandum* from Melissa G. Skinner to Holly A. Kuga dated December 27, 2000 (*Industry Support Memorandum*)). Based on information from these sources, the Department determined, pursuant to section 702(c)(4)(D) of the Act, that there is support for the petition as required by subparagraph (A). Specifically, the Department made the following determinations. For France, Germany, the Netherlands, and the United Kingdom, the petitioners established industry support representing over 50 percent of total production of the domestic like product. Therefore, the domestic producers or workers who support the petitions account for at least 25 percent of the total production of the domestic like product, and the requirements of section 702(c)(4)(A)(i) are met.

On December 19, 2000, the Ad Hoc Utilities Group (the Utilities Group) (Arizona Public Service Co.; Carolina Power & Light Co.; Commonwealth Edison Co.; Consumers Energy; Dominion Generation, Duke Energy Corp.; DTE Energy; Entergy Services, Inc.; First Energy Nuclear Operating Co.; Nuclear Management Co.; PSEG Nuclear LLC; Southern Nuclear Operating Co.; Union Electric Company (d/b/a AmerenUE); and Wolf Creek Nuclear Operating Corp.) filed a letter asserting that the Utilities Group members are domestic producers of LEU and that the petitioners lack industry support, because USEC produces less than 25 percent of domestic LEU. On December 20, 2000, Eurodif/Cogema and Urenco filed a submission claiming that the petitioners did not have standing in order to file the petitions. Both the Utilities Group and Eurodif/Cogema and Urenco argue that the petitioners are in the business of providing a service (*i.e.,* the enrichment of uranium), rather than manufacturing a product, and the countervailing duty law does not apply to services. In addition, they argue that the vast majority of the petitioners' production of enriched uranium is performed under a tolling arrangement, whereby the utilities provide the petitioners with converted uranium, and retain title to the input while the

petitioners enrich it. The utilities and foreign respondents argue that the utilities are the producers for these transactions.

During consultations, the governments and Delegation expressed the same views as the Utilities Group and Eurodif/Cogema and Urenco with respect to USEC's standing to file these petitions.

On December 21, 2000, the petitioners submitted a letter to rebut the Utilities Group's comments on industry support. The petitioners argue that the tolling regulation has no relevance in determining who is a U.S. producer or manufacturer of the domestic like product for standing purposes. In addition, the petitioners argue that the Utilities Group provided no factual support for its claim that its members are producers of LEU, and that it is not an interested party.

On December 22, 2000, the petitioners submitted additional comments with regard to the above comments made by the Utilities Group and Eurodif/Cogema and Urenco.

As explained in *The Petitions* section above, PACE filed a letter on December 26, 2000, joining the petitions.

On December 26, 2000, Eurodif/Cogema and Urenco submitted additional comments regarding their December 20, 2000, submission on industry support.

Based on our analysis of the comments received from the Utilities Group, Eurodif/Cogema and Urenco, and the petitioners, the Department determined that the utilities were not part of the domestic industry producing LEU. *See Industry Support Memorandum,* where we found that the utility companies do not engage in any manufacturing type of activities with respect to the production of LEU.

Because the Department determined that the utilities were not part of the domestic industry, the Department received no opposition from the LEU industry to the petitions. Therefore, the domestic producers or workers who support the petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for or opposition to the petitions. Thus, the requirements of section 702(c)(4)(A)(ii) are also met.

Accordingly, the Department determines that the petitions were filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act. *See* the *Initiation Checklist.*

Injury Test

Because France, Germany, the Netherlands, and the United Kingdom are ''Subsidies Agreement Countries'' within the meaning of section 701(b) of the Act, section 701(a)(2) applies to these investigations. Accordingly, the ITC must determine whether imports of the subject merchandise from these countries materially injure, or threaten material injury to, a U.S. industry.

Allegations of Subsidies

Section 702(b) of the Act requires the Department to initiate a countervailing duty proceeding whenever an interested party files, on behalf of an industry, a petition that: (1) alleges the elements necessary for an imposition of a duty under section 701(a); and (2) is accompanied by information reasonably available to petitioners supporting the allegations.

A. France

We are initiating an investigation of the following programs alleged in the petition to have provided countervailable subsidies to producers and exporters of the subject merchandise in France:

1. *Purchase of Enriched Uranium at Prices that Constitute ''More Than Adequate Remuneration''*
2. *Partial Exemption from Corporate Income Taxes*

B. Germany

We are initiating an investigation of the following programs alleged in the petition to have provided countervailable subsidies to producers and exporters of the subject merchandise in Germany:

1. *Enrichment Technology Research and Development Subsidies*
2. *Regional and City Enrichment Construction Subsidies*
3. *Forgiveness of Centrifuge Enrichment Capacity Subsidies*
4. *Federal Subsidies*

C. The Netherlands

We are initiating an investigation of the following programs alleged in the petition to have provided countervailable subsidies to producers and exporters of the subject merchandise in the Netherlands:

1. *Centrifuge Enrichment Technology Research & Development*
2. *1981 Equity Conversion*
3. *Subordinated Shareholder Loan provided by Ultra-Centrifuge Nederland N.V.*
4. *1998 Shareholder Loan*
5. *Subsidized Loan Forgiveness*
6. *Wet Investeringsrekening Law (WIR) Investment Incentives*
7. *Regional Investment Premiums*

D. The United Kingdom

We are initiating an investigation of the following programs alleged in the petition to have provided countervailable subsidies to producers and exporters of the subject merchandise in the United Kingdom:

1. *Forgiveness of Decommissioning Debt*
2. *Extraordinary Asset Write Downs Prior to Transfer of British Nuclear Fuels Ltd. Enrichment Facilities (BNFL)*
3. *1993 Debt Forgiveness*
4. *Loan-Stock Debt Forgiveness*
5. *Nuclear Industry Finance Act Loans and Loan Guarantees Under the Atomic Energy and Nuclear Industry Finance Acts*
6. *European Investment Bank Loans*
7. *Subordinated Shareholder Loan Provided to Urenco Ltd. by BNFL*
8. *Regional Development Grants (RDGs) to British Nuclear Fuels Limited Enrichment Ltd. That Are Tied to the Capenhurst Enrichment Facility and RDGs to BNFL That Are Attributable to Urenco Ltd.*
9. *Centrifuge Development Grant Tied to Capenhurst Facility*
10. *Fossil Fuel Levy*
11. *Financial Assistance Under the Electricity Act of 1989*

We are not initiating an investigation of the following programs alleged in the petition to have provided countervailable subsidies to producers and exporters of the subject merchandise in the United Kingdom.

1. Transfer of A3 Plant From BNFL to Urenco Ltd. at Less Than Adequate Remuneration

Petitioners allege that BNFL's sale of the A3 plant to Urenco Ltd. in 1995 was conducted at a price that was less than its book value, and, therefore constitutes a sale of a good by a government entity for less than adequate remuneration. In support of their contention, petitioners state that the cash price paid for the A3 plant (£29.3 million) was below the plant's true book value which, according to their estimations, should have been valued at 52.8 million.

Section 771(5)(E)(iv) of the Act states that the adequacy of remuneration shall be determined in relation to the prevailing market conditions which include price, quality, availability, marketability, and other conditions of purchase or sale. The mere fact that the A3 plant was allegedly sold at a price that was below its book value is not enough information to warrant initiating an investigation of a less than adequate remuneration allegation without any reference to prevailing market conditions for the good in question.

Therefore, we are not initiating on petitioners' less than adequate remuneration allegation on the grounds that petitioners have not provided sufficient information to warrant initiating an investigation of this program.

2. Extraordinary Write Down Taken by BNFL in 1993 Provided a Potential Benefit to Urenco Ltd.

In 1993, BNFL transferred its enrichment production at the Capenhurst facility to Urenco Ltd. in exchange for one-third ownership in Urenco Ltd. Petitioners state that when BNFL exchanged the Capenhurst facility for ownership in Urenco Ltd., BNFL incurred an extraordinary charge of £40 million to cover the restructuring of the enrichment operations. Petitioners claim that because of the non-transparency of Urenco's restructuring, they have been unable to determine how to attribute the entire £40 million written off by BNFL. However, petitioners contend that the one-third interest in Urenco Ltd. that BNFL gained may not have been a fair market exchange and that the £40 million charge taken by BNFL may have somehow provided subsidy benefits to Urenco Ltd. that were not reflected in the terms of the restructuring.

The only evidence that petitioners have provided in support of this allegation is a press article stating that BNFL made a £40 million charge to cover the merger of its Capenhurst uranium enrichment plant. However, petitioners provide no evidence to indicate that this charge should have somehow been attributed to Urenco Ltd. Furthermore, petitioners provide no information demonstrating how the £40 million charge allegedly taken by BNFL resulted in BNFL obtaining its one-third interest in Urenco Ltd. at less than adequate remuneration. As noted above, the adequacy of remuneration shall be determined in relation to the prevailing market conditions which include price, quality, availability, marketability, and other conditions of purchase or sale. Petitioners have not addressed any of these factors. On this basis, we are not initiating an investigation of petitioners' less than adequate remuneration allegation. However, because the 1993 corporate restructuring of the Urenco Group is involved in several allegations on which we are initiating investigations, during the course of this investigation we will request additional information from respondents regarding BNFL's extraordinary charge of £40 million.

Allegations and Evidence of Material Injury and Causation

The petitions allege that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the subsidization of individual and cumulated imports of the subject merchandise. Petitioners contend that the industry's injured condition is evident in the declining trends in net operating profits, net sales volumes, profit-to-sales ratios, and capacity utilization. The allegations of injury and causation are supported by relevant evidence including U.S. Customs import data, lost sales, and pricing information. We have assessed the allegations and supporting evidence regarding material injury and causation, and have determined that these allegations are properly supported by accurate and adequate evidence and meet the statutory requirements for initiation (*see Initiation Checklist* at Attachment II Re: Material Injury).

Initiation of Countervailing Duty Investigations

The Department has examined the countervailing duty petitions on low enriched uranium from France, Germany, the Netherlands, and the United Kingdom, and found that they comply with the requirements of section 702(b) of the Act. Therefore, in accordance with section 702(b) of the Act, we are initiating countervailing duty investigations to determine whether manufacturers, producers, or exporters of low enriched uranium from these countries receive subsidies. *See* the December 27, 2000, memoranda to the file (for each country) regarding the initiation of each investigation (public versions on file in the Central Records Unit of the Department of Commerce, Room B–099).

Distribution of Copies of the Petitions

In accordance with section 702(b)(3)(A) of the Act, a copy of the public version of each petition has been provided to the representatives of the governments of France, Germany, the Netherlands, and the United Kingdom, as well as to the Delegation of the European Community. We will attempt to provide a copy of the public version of each petition to each exporter named in the petition, as appropriate.

ITC Notification

Pursuant to section 702(d) of the Act, we have notified the ITC of these initiations.

Preliminary Determination by the ITC

The ITC will determine by January 22, 2001, whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, by reason of imports of low enriched uranium from France, Germany, the Netherlands, and the United Kingdom. A negative ITC determination for any country will result in the investigation being terminated with respect to that country; otherwise, the investigations will proceed according to statutory and regulatory time limits.

This notice is published pursuant to section 777(i) of the Act.

Dated: December 27, 2000.

Holly A. Kuga,

Acting Assistant Secretary for Import Administration.

[FR Doc. 01–385 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No. 00092–9279–01]

RIN 0693–ZA41

Announcing a Draft Federal Information Processing Standard for the Keyed-Hash Message Authentication Code (HMAC), and Request for Comments

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice; Request for Comments.

SUMMARY: This notice announces a draft Federal Information Processing Standard (FIPS) for the Keyed-Hash Message Authentication Code (HMAC), for public review and comment.

This draft FIPS describes a keyed-hash message authentication code (HMAC), A MECHANISM FOR MESSAGE AUTHENTICATION USING CRYPTOGRAPHIC HASH FUNCTIONS, HMAC can be used with any FIPS-approved cryptographic hash function, in combination with a shared secrete key. The cryptographic strength of HMAC depends on the properties of the underlying hash function. The HMAC specification in this draft FIPS is a generalization of HMAC as specified in Internet RFC 2104, HMAC, Keyed-Hashing for Message Authentication, and ANSI X9.71, Keyed Hash Message Authentication Code.

Prior to the submission of this proposed standard to the Secretary of Commerce for review and approval, it is essential that consideration is given to

the needs and views of the public, users, the information technology industry, and Federal, State and local government organizations. The purpose of this notice is to solicit such views.

DATES: Comments must be received on or before April 5, 2001.

ADDRESSES: Written comments may be sent to: Chief, Computer Security Division, Information Technology Laboratory, Attention: Comments on the draft FIPS for HMAC, 100 Bureau Drive—Stop 8930 National Institute of Standards and Technology, Gaithersburg, MD 20899–8930.

Electronic comments may also be sent to: ''HMAC@nist.gov''.

This draft FIPS is available electronically at: http://www.nist.gov/hmac/ or http://csrc.nist.gov/publications/drafts.html.

Comments received in response to this notice will be published electronically at http://www.nist.gov/hmac/.

FOR FURTHER INFORMATION CONTACT: Elaine Barker, Computer Security Division, National Institute of Standards and Technology, Gaithersburg, MD 20899–8930, telephone (301) 975–2911, email: elaine.barker@nist.gov.

SUPPLEMENTARY INFORMATION: This draft FIPS for The Keyed-Hash Message Authentication Code (HMAC) specifies an algorithm for applications requiring message authentication. Message authentication is achieved via the construction of a message authentication code (MAC). MACs based on cryptographic hash functions are known as HMACs.

The purpose of a MAC is to authenticate both the source of a message and its integrity without the use of any additional mechanisms. HMACs have two functionally distinct parameters, message input and a secret key known only to the message originator and intended receiver(s). Additional applications of keyed hash functions include their use in challege-response identification protocols for computing responses. which are a function of both a secret key and a challenge message.

An HMAC function is used by the originator to produce a value (the MAC) that is formed by condensing the secret key and the message input. The MAC is typically sent to the message receiver along with the message. The receiver computes the MAC on the received message using the same key and HMAC function as was used by the originator, and compares the result computed with the received MAC. If the two values match, the message has been correctly received, and the receiver is assured that the message originator is a member of the community of users that share the key.

Authority: Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology after approval by the Secretary of Commerce pursuant to section 5131 of the Information Technology Management Reform Act of 1996 and the Computer Security Act of 1987, Public Law 100–2235.

E.O. 12866: This notice has been determined to be non-significant for the purposes of E. O. 12866.

Dated: January 2, 2001.

Karen H. Brown,

Deputy Director, NIST.

[FR Doc. 01–381 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–CN–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[I.D. 122800C]

Availability of a Final Environmental Impact Statement for the Tacoma Water Department Habitat Conservation Plan, King County, WA

AGENCIES: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration, Commerce; Fish and Wildlife Service (FWS), Interior.

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of a Final Environmental Impact Statement (FEIS) for public review. The FEIS addresses the proposed issuance of Incidental Take Permits (permits) to the City of Tacoma, WA, Department of Public Utilities, Water Division (Tacoma Water). The proposed permits relate to water withdrawal, forest management, and timber harvest on City of Tacoma lands in King County, WA. Tacoma Water submitted applications on December 23, 1999, to the FWS and the NMFS (together, the Services) for permits pursuant to the Endangered Species Act (the Act). The proposed permits would authorize take of the following endangered or threatened species incidental to otherwise lawful management activities: gray wolf (*Canis lupis*), bald eagle (*Haliaeetus leucocephalus*), marbled murrelet (*Brachyramphus marmoratus marmoratus*), northern spotted owl (*Strix occidentalis caurina*), grizzly bear (*Ursus arctos*), Canada lynx (*Lynx canadensis*), Puget Sound chinook salmon (*Oncorhynchus tshawytscha*), and bull trout (*Salvelinus confluentus*). Tacoma Water is also seeking coverage for 24 currently unlisted species under specific provisions of the permits, should these species be listed in the future. The duration of the proposed permits is 50 years. This notice is provided pursuant to the ESA, and National Environmental Policy Act (NEPA) regulations.

DATES: We will issue a Record of Decision and make a final permit decision no sooner than 30 days after publication of this notice.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** for addresses of locations where you may review copies of the documents.

FOR FURTHER INFORMATION CONTACT: Mr. Tim Romanski, Project Biologist, FWS, 510 Desmond Drive. S.E., Suite 102, Lacey, Washington, 98503–1273, (360) 753–5823; or Mike Grady, Project Biologist, NMFS, 7600 Sand Point Way NE, Bldg. 1, Seattle, Washington, 98115–0070, (206) 526–4645.

SUPPLEMENTARY INFORMATION:

Availability of Documents

Copies of the Statement, and all associated documents are available for review at the following libraries:

The Olympia Timberland Library, Reference Desk, 313 8th Avenue SE, Olympia, WA, (360)352–0595

Tacoma Main Public Library, 1102 Tacoma Avenue South, Tacoma, WA, (253)591–5666

Enumclaw City Library, 1700 1st Street, Enumclaw, WA, (360)825–2938; Auburn Public Library, 808 9th Street SE, Auburn, WA, (253)931–3918

The Seattle Public Library, Government Publications Desk, 1000 4th Avenue, Seattle, WA, (206)386–4636.

The documents are also available electronically on the World Wide Web at http://www.r1.fws.gov/. Requests for documents or CD ROMs should be made by calling the FWS at (360)534–9330.

Section 9 of the Act and Federal regulations prohibit the ''taking'' of a species listed as endangered or threatened. The term take is defined under the Act to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Harm is defined by the FWS to include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns,

including breeding, feeding, and sheltering (50 CFR 17.3). The NMFS definition of harm includes significant habitat modification or degradation where it actually kills or injures fish or wildlife by significantly impairing essential behavioral patterns, including breeding, spawning, rearing, feeding, and sheltering (64 FR 60727, November 8, 1999).

The Services may issue permits, under limited circumstances, to take listed species incidental to, and not for the purpose of, otherwise lawful activities. FWS regulations governing permits for endangered species are found at 50 CFR 17.22; and, regulations governing permits for threatened species are found at 50 CFR 17.32. NMFS regulations governing permits for threatened and endangered species are found at 50 CFR 222.307.

Background

Tacoma Water owns land and conducts management activities in the Green River Watershed in King County, WA. Management activities include the following: (1) operation of a water diversion dam and associated facilities (Headworks) on the Green River; (2) forest management on approximately 14,888 acres (approximately 6025 hectares)of land upstream of the Headworks diversion dam on both sides of the river; and (3) well field operations (North Fork Well Field) located approximately 5 miles (8 kilometers) upstream of the Headworks. Tacoma Water operates and manages the Headworks, watershed lands, and the North Fork Well Field as the principal source of municipal and industrial water for the City of Tacoma and portions of Pierce and King Counties. Howard Hanson Dam (Dam) and Howard Hanson Reservoir (Reservoir), owned and operated by the Army Corps of Engineers (Corps), are also located on the Green River, upstream of the Headworks. City lands in the watershed are adjacent to the Dam and Reservoir.

Current trends in planned population growth within the Puget Sound region create a need for Tacoma Water to explore possibilities for increasing its water supply capabilities. To meet forecasted demands, Tacoma has developed two separate but related plans. The first of these, the Second Supply Project, involves improvements at the Headworks and the construction of a 33.5-mile (53.9 Kilometers) long pipeline from the Headworks to the City of Tacoma. Upstream fish passage around Tacoma's Headworks and the Dam would be provided by the City of Tacoma as partial mitigation for the Second Supply Project. This project is the subject of a State Environmental Policy Act review in a document entitled ''Final Supplemental Environmental Impact Statement for the Second Supply Project, October 18, 1994,'' prepared by Tacoma Water. The second related plan was developed in conjunction with the Corps (and in cooperation with the Services, the Washington Department of Fish and Wildlife, Washington Department of Ecology, and the Muckleshoot Indian Tribe), to increase the volume of water stored behind the Dam during non-flood control periods (late spring, summer, and early fall). Known as the Additional Water Storage Project, this plan incorporates restoration and mitigation measures (including downstream fish passage) to alleviate the historical barrier to migrating salmon created by the Dam. The size of the Dam will not change as a result of the Additional Water Storage Project. This Additional Water Storage Project is the subject of a NEPA review in a document entitled ''Additional Water Storage Project, Final Feasibility Study Report and EIS, Howard Hanson Dam, Green River, Washington, August, 1998,'' prepared by the Seattle District of the Corps.

Tacoma Water's activities associated with the Second Supply Project, the Additional Water Storage Project, and other management activities on the City's watershed lands have the potential to impact species subject to protection under the Act. Section 10 of the Act contains provisions for the issuance of Incidental Take Permits to non-Federal landowners for the take of endangered and threatened species, provided the take is incidental to otherwise lawful activities, and will not appreciably reduce the likelihood of the survival and recovery of the species in the wild. In addition, the applicant must prepare and submit to the Services for approval an Habitat Conservation Plan(HCP) containing a program for minimizing and mitigating, to the maximum extent practicable, all take associated with the proposed activities. The applicant must also ensure that adequate funding for the Plan will be provided.

Tacoma Water has developed an HCP with technical assistance from the Services, to obtain permits for their activities in the Green River Watershed. Activities proposed for coverage under the permits include the following.

(1) Water withdrawal at the Headworks for Municipal and Industrial Water Supply. This withdrawal would reduce flows, have concomitant habitat effects downstream, include the bypass of fish at the Headworks intake, and inundate the small impoundment area.

(2) Water withdrawal from the North Fork Well Field for Municipal and Industrial Water Supply, which would potentially reduce flows in the North Fork Green River above the Reservoir.

(3) Construction of Headworks improvements (anticipated to occur during a 2- year period).

Such construction would cause:

(a) bypassing of fish at the Headworks intake during construction;

(b) raising the existing diversion dam by approximately 6.5 ft (approximately 2 meters) which would extend the inundation pool to about 2,570 ft (approximately 783 meters) upstream of the Headworks diversion;

(c) realigning and enlarging the existing intake and adding upgraded fish screens and bypass facilities for downstream passage;

(d) reshaping the Green River channel downstream of the existing diversion to accommodate the installation of an efficient trap-and-haul facility for upstream fish passage;

(e) installing a new trap-and-haul facility for upstream fish passage; and,

(f) installation, monitoring, and maintenance of the instream structures in the impoundment for the Headworks dam raise fisheries mitigation.

(4) Operating a downstream fish bypass facility at the Headworks.

(5) Tacoma watershed forest management activities, consisting of:

(a) watershed patrol and inspection;

(b) forest road construction, maintenance, and use;

(c) forest road culvert removal, replacement, and maintenance;

(d) timber harvest and hauling; and,

(e) silvicultural activities (e.g., planting, thinning, and inventorying trees).

(6) Monitoring of downstream fish passage through a proposed fish passage facility at the Dam, associated with the Additional Water Supply Project.

(7) Monitoring and maintenance of Additional Water Supply Project fish habitat restoration projects and Additional Water Supply Project fish and wildlife habitat mitigation projects.

(8) Potential restoration of anadromous fish above the Dam by trapping and hauling adults returning to the Headworks, and possible planting of hatchery juveniles if found to be beneficial to restoration.

The Services formally initiated an environmental review of the project through a **Federal Register** notice on August 21, 1998 (63 FR 44918). This notice also announced a 30-day public scoping period during which other agencies, tribes, and the public were invited to provide comments and suggestions regarding issues and

alternatives to be considered. A second **Federal Register** notice was published following the scoping period on January 20, 1999 (64 FR 3066), announcing the decision to prepare an Environmental Impact Statement. A Draft Environmental Impact Statement (DEIS) was subsequently produced and made available for a 60-day public comment period on January 14, 2000 (65 FR 2390). The comment period was extended for 17 days to March 14, 2000 (65 FR 13947), in direct response to requests from the public. This resulted in a total comment period of 77 days. Comments received on the DEIS and responses to those comments are included in the FEIS.

The analyses in the FEIS are done in two parts; one covering the alternatives for water withdrawal activities, and the other covering alternatives for land management activities in the upper watershed. Three water withdrawal alternatives are analyzed in detail, including: (1) the no action alternative; (2) the proposed HCP alternative; and, (3) an alternative involving the construction of a new water withdrawal facility approximately 30 miles downstream of the existing Tacoma Headworks. Four additional water withdrawal options were identified during scoping, but they are not analyzed in detail as alternatives to the proposed action because they would not accomplish Tacoma's objective of meeting current and future water demands, and/or because highly speculative information would be required to adequately analyze impacts.

Three alternatives are analyzed for Tacoma Water's watershed management, including: (1) the no action alternative; (2) the proposed HCP alternative; and, (3) a no commercial timber harvest alternative. A fourth watershed management option was identified during public scoping, but it was not analyzed in detail as an alternative to the proposed action because it would not accomplish Tacoma's objective of managing its watershed lands to protect water quality. Lastly, a fifth alternative was identified during public review of the DEIS, involving the state Forests and Fish Report. However, this was not fully analyzed because the No Action and proposed conservation measures surpassed this report, due to agreements Tacoma Water has with other stakeholders.

All water withdrawal and watershed land management alternatives (except the no action alternatives) would provide incidental take coverage for the same 32 fish and wildlife species. These include the following listed species: gray wolf, bald eagle, marbled murrelet, northern spotted owl, grizzly bear, Canada lynx, Puget Sound chinook salmon, and the bull trout. Coverage is also being requested for 24 currently unlisted species (including anadromous and resident fish) under specific provisions of the permits, should these species be listed in the future. The duration of the proposed permits and Plan is 50 years.

This notice is provided pursuant to section 10(a) of the Act, and NEPA regulations. The Services will evaluate the application, associated documents, and comments submitted thereon to determine whether the application meets the requirements of the Act and the NEPA. If it is determined that the requirements are met, permits will be issued for the incidental take of all covered species.

Dated: December 28, 2000.

Daniel Diggs,

Acting Regional Director, Fish and Wildlife Service, Region 1, Portland, Oregon.

Dated: January 2, 2001.

Margaret Lorenz,

Acting Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 01–374 Filed 1–4–01; 8:45 am]

BILLING CODE: 3510–22 –S, 4310–55 –S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 010201C]

North Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of emergency meetings of the North Pacific Fishery Management Council (Council) and its Advisory Panel.

SUMMARY: The North Pacific Fishery Management Council and its Advisory Panel will meet in Seattle in early January to consult with NMFS on Steller sea lion protective measures for 2001 and 2001.

DATES: The meeting of the Advisory Panel will be held on January 11, 2001. The Council meeting will be held January 12–13, 2001.

ADDRESSES: The meetings will be held at the Doubletree Hotel, Seattle Airport, 18740 Pacific Highway South, Seattle, WA.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Council staff, telephone: 907–271–2809.

SUPPLEMENTARY INFORMATION: All meetings will be held at the Hotel. The Advisory Panel will meet on Thursday, January 11, beginning at 8:00 a.m., concluding by 6:00 p.m. The Council will begin at 8:00 a.m. on Friday, January 12, and may continue into Saturday, January 13th, if necessary. Topics for both meetings include:

1. Consult with NMFS on emergency rule proposed for January 20–July 20, 2001.

2. NMFS proposed regulations for July 21–December 31, 2001; recommend changes as appropriate.

3. Establish a schedule for development of protective measures for 2002.

4. Develop schedule and proposal for utilizing expertise of the National Academy of Sciences to conduct an independent scientific review of the November 30, 2000 biological opinion and it's underlying hypothesis and reasonable and prudent alternatives.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Helen Allen at 907–271–2809 at least 7 working days prior to the meeting date.

Dated: January 2, 2001.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–375 Filed 1–4–01; 8:45 am]

BILLING CODE: 3510–22 –S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Fair Market Value Analysis for a Fiber Optic Cable Permit in National Marine Sanctuaries

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of availability.

SUMMARY: Notice is hereby given that NOAA is requesting comments on the report ''Fair Market Value Analysis for a Fiber Optic Cable Permit in National Marine Sanctuaries'' and two peer reviews of this report. The report and peer reviews are available for download at http://www.sanctuaries.nos.noaa.gov/news/newsbboard/newsbboard.html or by requesting an electronic or hard copy. Requests can be made by sending an email to submarine.cables@noaa.gov (subject line ''Request for Fair Market Value Analysis'') or by calling Matt Brookhart at (301) 713–3125 x140.

DATES: Comments on this notice must be received by January 18, 2001.

ADDRESSES: Address all comments regarding this notice to Matt Brookhart, Conservation Policy and Planning Branch, Office of National Marine Sanctuaries, 1305 East-West Highway, 11th Floor, Silver Spring, MD 20910, Attention: Fair Market Value Analysis. Comments may also be submitted by email to: *submarine.cables@noaa.gov,* subject line ''Fair Market Value Analysis.''

FOR FURTHER INFORMATION CONTACT: Helen Golde, (301) 713–3125 x152.

SUPPLEMENTARY INFORMATION: The Office of National Marine Sanctuaries has issued several special-use permits to companies seeking to install fiber optic cables in National Marine Sanctuaries. The Sanctuary statute allows ONMS to permit the presence of cables on the sanctuaries' seafloor should it decide to do so. If an application is approved, ONMS may collect certain administrative and monitoring fees. In addition, ONMS is entitled to receive fair market value for the permitted use of sanctuary resources.

The report ''Fair Market Value Analysis for a Fiber Optic Cable Permit in National Marine Sanctuaries'' presents an assessment of fair market value for the use of National Marine Sanctuary resources for a fiber optic cable. Proper stewardship of sanctuary resources and open and equitable relations with telecommunication industry interests require a clear and consistent policy in this matter. The content of this report is based on dozens of industry and government sources and draws on the collaboration and review of numerous experts in the business, legal and technical arenas.

Once finalized, the fee structure proposed in this report will be used to assess fees (as stated in their respective special use permits) for cables already installed in the Olympic Coast and Stellwagen Bank National Marine Sanctuaries. In addition, this structure will provide the basis for future fair market value assessment of submarine cable permit applications in National Marine Sanctuaries. Comments on the report and peer reviews should focus on the methodology employed and the conclusions that it reached.

Dated: December 29, 2000.

John Oliver,

Chief Financial Officer, National Ocean Service.

[FR Doc. 01–387 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. 991027289–0263–02]

RIN 0651–AB09

Utility Examination Guidelines

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is publishing a revised version of guidelines to be used by Office personnel in their review of patent applications for compliance with the ''utility'' requirement of 35 U.S.C. 101. This revision supersedes the Revised Interim Utility Examination Guidelines that were published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136 (2000); and correction at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67 (2000).

DATES: The Guidelines are effective as of January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Mark Nagumo by telephone at (703) 305–8666, by facsimile at (703) 305–9373, by electronic mail at ''mark.nagumo@uspto.gov,'' or by mail marked to his attention addressed to the Office of the Solicitor, Box 8, Washington, DC 20231; or Linda Therkorn by telephone at (703) 305–9323, by facsimile at (703) 305–8825, by electronic mail at ''linda.therkorn@uspto.gov,'' or by mail marked to her attention addressed to Box Comments, Commissioner for Patents, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: As of the publication date of this notice, these Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the ''utility'' requirement of 35 U.S.C. 101. Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

I. Discussion of Public Comments

The Revised Interim Utility Examination Guidelines published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136, Feb. 29, 2000, with a correction at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67, Feb. 15, 2000, requested comments from the public. Comments were received from 35 individuals and 17 organizations. The written comments have been carefully considered.

Overview of Comments

The majority of comments generally approved of the guidelines and several expressly stated support for the three utility criteria (specific, substantial, and credible) set forth in the Guidelines. A few comments addressed particular concerns with respect to the coordinate examiner training materials that are available for public inspection at the USPTO website, *www.uspto.gov.* The comments on the training materials will be taken under advisement in the revision of the training materials. Consequently, those comments are not specifically addressed below because they do not impact the content of the Guidelines. Comments received in response to the request for comments on the ''Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1 'Written Description' Requirement,'' 64 FR 71427, Dec. 21, 1999; 1231 O.G. 123, Feb. 29, 2000, which raised issues pertinent to the utility requirement are also addressed below.

Responses to Specific Comments

(1) *Comment:* Several comments state that while inventions are patentable, discoveries are not patentable. According to the comments, genes are discoveries rather than inventions. These comments urge the USPTO not to issue patents for genes on the ground that genes are not inventions. *Response:* The suggestion is not adopted. An inventor can patent a discovery when the patent application satisfies the statutory requirements. The U.S.

Constitution uses the word ''discoveries'' where it authorizes Congress to promote progress made by inventors. The pertinent part of the Constitution is Article 1, section 8, clause 8, which reads: ''The Congress shall have power * * * To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.''

When Congress enacted the patent statutes, it specifically authorized issuing a patent to a person who ''invents or discovers'' a new and useful composition of matter, among other things. The pertinent statute is 35 U.S.C. 101, which reads: ''Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.'' Thus, an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.

If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the ''utility'' requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.

(2) *Comment:* Several comments state that a gene is not a new composition of matter because it exists in nature, and/or that an inventor who isolates a gene does not actually invent or discover a patentable composition because the gene exists in nature. These comments urge the USPTO not to issue patents for genes on the ground that genes are products of nature. Others state that naturally occurring DNAs are part of our heritage and are not inventions. Another comment expressed concern that a person whose body includes a patented gene could be guilty of patent infringement. *Response:* The comments are not adopted. A patent claim directed to an isolated and purified DNA molecule could cover, *e.g.,* a gene excised from a natural chromosome or a synthesized DNA molecule. An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.

Patenting compositions or compounds isolated from nature follows well-established principles, and is not a new practice. For example, Louis Pasteur received U.S. Patent 141,072 in 1873, claiming ''[y]least, free from organic germs of disease, as an article of manufacture.'' Another example is an early patent for adrenaline. In a decision finding the patent valid, the court explained that compounds isolated from nature are patentable: ''even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it [adrenaline] available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.'' *Parke-Davis & Co.* v. *H. K. Mulford Co.,* 189 F. 95, 103 (S.D.N.Y. 1911) (J. Learned Hand).

In a more recent case dealing with the prostaglandins PGE_2 and PGE_3, extracted from human or animal prostate glands, a patent examiner had rejected the claims, reasoning that ''inasmuch as the 'claimed compounds are naturally occurring' * * * they therefore 'are not 'new' within the connotation of the patent statute.' '' *In re Bergstrom,* 427 F.2d 1394, 1397, 166 USPQ 256, 259 (CCPA 1970). The Court reversed the Patent Office and explained the error: ''what appellants claim—pure PGE_2 and PGE_3—is not 'naturally occurring.' Those compounds, as far as the record establishes, do not exist in nature in pure form, and appellants have neither merely discovered, nor claimed sufficiently broadly to encompass, what has previously existed in fact in nature's storehouse, albeit unknown, or what has previously been known to exist.'' *Id.* at 1401, 166 USPQ at 261–62. Like other chemical compounds, DNA molecules are eligible for patents when isolated from their natural state and purified or when synthesized in a laboratory from chemical starting materials.

A patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature. Thus, the concern that a person whose body ''includes'' a patented gene could infringe the patent is misfounded. The body does not contain the patented, isolated and purified gene because genes in the body are not in the patented, isolated and purified form. When the patent issued for purified adrenaline about one hundred years ago, people did not infringe the patent merely because their bodies naturally included unpurified adrenaline.

(3) *Comment:* Several comments suggested that the USPTO should seek guidance from Congress as to whether naturally occurring genetic sequences are patentable subject matter. *Response:* The suggestion is not adopted. Congress adopted the current statute defining patentable subject matter (35 U.S.C. 101) in 1952. The legislative history indicates that Congress intended ''anything under the sun that is made by man'' to be eligible for patenting. S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952). The Supreme Court interprets the statute to cover a ''nonnaturally occurring manufacture or composition of matter—a product of human ingenuity.'' *Diamond* v. *Chakrabarty,* 447 U.S. 303, 309, 206 USPQ 193, 197 (1980). Thus, the intent of Congress with regard to patent eligibility for chemical compounds has already been determined: DNA compounds having naturally occurring sequences are eligible for patenting when isolated from their natural state and purified, and when the application meets the statutory criteria for patentability. The genetic sequence data represented by strings of the letters A, T, C and G alone is raw, fundamental sequence data, i.e., nonfunctional descriptive information. While descriptive sequence information alone is not patentable subject matter, a new and useful purified and isolated DNA compound described by the sequence is eligible for patenting, subject to satisfying the other criteria for patentability.

(4) *Comment:* Several comments state that patents should not issue for genes because the sequence of the human genome is at the core of what it means to be human and no person should be able to own/control something so basic. Other comments stated that patents should be for marketable inventions and not for discoveries in nature. *Response:* The comments are not adopted. Patents do not confer ownership of genes, genetic information, or sequences. The patent system promotes progress by securing a complete disclosure of an invention to the public, in exchange for the inventor's legal right to exclude other people from making, using, offering for sale, selling, or importing

the composition for a limited time. That is, a patent owner can stop infringing activity by others for a limited time.

Discoveries from nature have led to marketable inventions in the past, but assessing the marketability of an invention is not pertinent to determining if an invention has a specific, substantial, and credible use. ''[D]evelopment of a product to the extent that it is presently commercially salable in the marketplace is not required to establish 'usefulness' within the meaning of § 101.'' *In re Langer,* 503 F.2d 1380, 1393, 183 USPQ 288, 298 (CCPA 1974). Inventors are entitled to patents when they have met the statutory requirements for novelty, nonobviousness and usefulness, and their patent disclosure adequately describes the invention and clearly teaches others how to make and use the invention. The utility requirement, as explained by the courts, only requires that the inventor disclose a practical or real world benefit available from the invention, i.e., a specific, substantial and credible utility. As noted in a response to other comments, it is a long tradition in the United States that discoveries from nature which are transformed into new and useful products are eligible for patents.

(5) *Comment:* Several comments state that the Guidelines mean that anyone who discovers a gene will be allowed a broad patent covering any number of possible applications even though those uses may be unattainable and unproven. Therefore, according to these comments, gene patents should not be issued. *Response:* The comment is not adopted. When a patent claiming a new chemical compound issues, the patentee has the right to exclude others from making, using, offering for sale, selling, or importing the compound for a limited time. The patentee is required to disclose only one utility, that is, teach others how to use the invention in at least one way. The patentee is not required to disclose all possible uses, but promoting the subsequent discovery of other uses is one of the benefits of the patent system. When patents for genes are treated the same as for other chemicals, progress is promoted because the original inventor has the possibility to recoup research costs, because others are motivated to invent around the original patent, and because a new chemical is made available as a basis for future research. Other inventors who develop new and nonobvious methods of using the patented compound have the opportunity to patent those methods.

(6) *Comment:* One comment suggests that the USPTO should not allow the patenting of ESTs because it is contrary to indigenous law, because the Supreme Court's *Diamond* v. *Chakrabarty* decision was a bare 5-to-4 decision, because it would violate the Thirteenth Amendment of the U.S. Constitution, because it violates the novelty requirement of the patent laws, because it will exacerbate tensions between indigenous peoples and western academic/research communities and because it will undermine indigenous peoples' own research and academic institutions. The comment urges the USPTO to institute a moratorium on patenting of life forms and natural processes. *Response:* The comments are not adopted. Patents on chemical compounds such as ESTs do not implicate the Thirteenth Amendment. The USPTO must administer the patent statutes as the Supreme Court interprets them. When Congress enacted § 101, it indicated that ''anything under the sun that is made by man'' is subject matter for a patent. S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952). The Supreme Court has interpreted § 101 many times without overturning it. *See, e.g., Diamond* v. *Diehr,* 450 U.S. 175, 209 USPQ 1 (1981) (discussing cases construing section 101). Under United States law, a patent applicant is entitled to a patent when an invention meets the patentability criteria of title 35. Thus, ESTs which meet the criteria for utility, novelty, and nonobviousness are eligible for patenting when the application teaches those of skill in the art how to make and use the invention.

(7) *Comment:* Several comments state that patents should not issue for genes because patents on genes are delaying medical research and thus there is no societal benefit associated with gene patents. Others state that granting patents on genes at any stage of research deprives others of incentives and the ability to continue exploratory research and development. Some comment that patentees will deny access to genes and our property (our genes) will be owned by others. *Response:* The comments are not adopted. The incentive to make discoveries and inventions is generally spurred, not inhibited, by patents. The disclosure of genetic inventions provides new opportunities for further development. The patent statutes provide that a patent must be granted when at least one specific, substantial and credible utility has been disclosed, and the application satisfies the other statutory requirements. As long as one specific, substantial and credible use is disclosed and the statutory requirements are met, the USPTO is not authorized to withhold the patent until another, or better, use is discovered. Other researchers may discover higher, better or more practical uses, but they are advantaged by the starting point that the original disclosure provides. A patent grants exclusionary rights over a patented composition but does not grant ownership of the composition. Patents are not issued on compositions in the natural environment but rather on isolated and purified compositions.

(8) *Comment:* Several comments stated that DNA should be considered unpatentable because a DNA sequence by itself has little utility. *Response:* A DNA sequence—*i.e.,* the sequence of base pairs making up a DNA molecule—is simply one of the properties of a DNA molecule. Like any descriptive property, a DNA sequence itself is not patentable. A purified DNA *molecule* isolated from its natural environment, on the other hand, is a chemical compound and is patentable if all the statutory requirements are met. An isolated and purified DNA molecule may meet the statutory utility requirement if, *e.g.,* it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene. Therefore, a DNA molecule is not *per se* unpatentable for lack of utility, and each application claim must be examined on its own facts.

(9) *Comment:* One comment states that the disclosure of a DNA sequence has inherent value and that possible uses for the DNA appear endless, even if no single use has been worked out. According to the comment, the ''basic social contract of the patent deal'' requires that such a discovery should be patentable, and that patenting should be ''value-blind.'' *Response:* The comment is not adopted. The Supreme Court did not find a similar argument persuasive in *Brenner* v. *Manson,* 383 U.S. 519 (1966). The courts interpret the statutory term ''useful'' to require disclosure of at least one available practical benefit to the public. The Guidelines reflect this determination by requiring the disclosure of at least one specific, substantial, and credible utility. If no such utility is disclosed or readily apparent from an application, the Office should reject the claim. The applicant may rebut the Office position by showing that the invention does have a specific, substantial, and credible utility that would have been recognized by one of skill in the art at the time the application was filed.

(10) *Comment:* Several comments stated that the scope of patent claims directed to DNA should be limited to applications or methods of using DNA, and should not be allowed to

encompass the DNA itself. *Response:* The comment is not adopted. Patentable subject matter includes both ''process[es]'' and ''composition[s] of matter.'' 35 U.S.C. 101. Patent law provides no basis for treating DNA differently from other chemical compounds that are compositions of matter. If a patent application claims a composition of matter comprising DNA, and the claims meet all the statutory requirements of patentability, there is no legal basis for rejecting the application.

(11) *Comment:* Several comments stated that DNA patent claim scope should be limited to uses that are disclosed in the patent application and that allowing patent claims that encompass DNA itself would enable the inventor to assert claims to ''speculative'' uses of the DNA that were not foreseen at the time the patent application was filed. *Response:* The comment is not adopted. A patent on a composition gives *exclusive* rights to the composition for a limited time, even if the inventor disclosed only a single use for the composition. Thus, a patent granted on an isolated and purified DNA composition confers the right to exclude others from *any* method of using that DNA composition, for up to 20 years from the filing date. This result flows from the language of the statute itself. When the utility requirement and other requirements are satisfied by the application, a patent granted provides a patentee with the right to exclude others from, *inter alia,* ''using'' the patented composition of matter. *See* 35 U.S.C. 154. Where a new use is discovered for a patented DNA composition, that new use may qualify for its own process patent, notwithstanding that the DNA composition itself is patented.

By statute, a patent is required to disclose one practical utility. If a well-established utility is readily apparent, the disclosure is deemed to be implicit. If an application fails to disclose one specific, substantial, and credible utility, and the examiner discerns no well-established utility, the examiner will reject the claim under section 101. The rejection shifts the burden to the applicant to show that the examiner erred, or that a well-established utility would have been readily apparent to one of skill in the art. The applicant cannot rebut the rejection by relying on a utility that would not have been readily apparent at the time the application was filed. *See, e.g., In re Wright,* 999 F.2d 1557, 1562–63, 27 USPQ2d 1510, 1514 (Fed. Cir. 1993) (''developments occurring after the filing date of an application are of no significance regarding what one skilled in the art believed as of the filing date'').

(12) *Comment:* Several comments stated that DNA should be freely available for research. Some of these comments suggested that patents are not necessary to encourage additional discovery and sequencing of genes. Some comments suggested that patenting of DNA inhibits biomedical research by allowing a single person or company to control use of the claimed DNA. Another comment expressed concern that patenting ESTs will impede complete characterization of genes and delay or restrict exploration of genetic materials for the public good. *Response:* The scope of subject matter that is eligible for a patent, the requirements that must be met in order to be granted a patent, and the legal rights that are conveyed by an issued patent, are all controlled by statutes which the USPTO must administer. ''Whoever invents or discovers any new and useful * * * composition of matter * * * may obtain a patent therefor.'' 35 U.S.C. 101. Congress creates the law and the Federal judiciary interprets the law. The USPTO must administer the laws as Congress has enacted them and as the Federal courts have interpreted them. Current law provides that when the statutory patentability requirements are met, there is no basis to deny patent applications claiming DNA compositions, or to limit a patent's scope in order to allow free access to the use of the invention during the patent term.

(13) *Comment:* Several comments suggested that DNA sequences should be considered unpatentable because sequencing DNA has become so routine that determining the sequence of a DNA molecule is not inventive. *Response:* The comments are not adopted. A DNA sequence is not patentable because a sequence is merely descriptive information about a molecule. An isolated and purified DNA molecule may be patentable because a molecule is a ''composition of matter,'' one of the four classes of invention authorized by 35 U.S.C. 101. A DNA molecule must be *nonobvious* in order to be patentable. Obviousness does not depend on the amount of work required to characterize the DNA molecule. *See* 35 U.S.C. 103(a) (''Patentability shall not be negatived by the manner in which the invention was made.''). As the nonobviousness requirement has been interpreted by the U.S. Court of Appeals for the Federal Circuit, whether a claimed DNA molecule would have been obvious depends on whether a molecule having the particular *structure* of the DNA would have been obvious to one of ordinary skill in the art at the time the invention was made. *See, e.g., In re Deuel,* 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995) (''[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious.''); *see also, In re Bell,* 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993).

(14) *Comment:* One comment suggested that genes ought to be patentable only when the complete sequence of the gene is disclosed and a function for the gene product has been determined. *Response:* The suggestion is not adopted. To obtain a patent on a chemical compound such as DNA, a patent applicant must adequately describe the compound and must disclose how to make and use the compound. 35 U.S.C. 101, 112. ''An adequate written description of a DNA * * * requires a precise definition, *such as* by structure, formula, chemical name, or physical properties.'' *Univ. of California* v. *Eli Lilly & Co.,* 119 F.3d 1559, 1556, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997) (emphasis added, internal quote omitted). Thus, describing the complete chemical structure, *i.e.,* the DNA sequence, is one method of describing a DNA molecule but it is not the only method. In addition, the utility of a claimed DNA does not necessarily depend on the function of the encoded gene product. A claimed DNA may have a specific and substantial utility because, *e.g.,* it hybridizes near a disease-associated gene or it has a gene-regulating activity.

(15) *Comment:* One comment stated that the specification should ''disclose the invention,'' including why the invention works and how it was developed. *Response:* The comment is not adopted. The comment is directed more to the requirements imposed by 35 U.S.C. 112 than to those of 35 U.S.C. 101. To satisfy the enablement requirement of 35 U.S.C. 112, ¶ 1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement of 35 U.S.C. 112, ¶ 1, the description must show that the applicant was in possession of the claimed invention at the time of filing. If all the requirements under 35 U.S.C. 112, ¶1, are met, there is no statutory basis to require disclosure of why an invention works or how it was developed. ''[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works.'' *Newman* v. *Quigg,*

877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989).

(16) *Comment:* One comment suggested that patents should ''allow for others to learn from and improve the invention.'' The comment suggested that claims to patented plant varieties should not prohibit others from using the patented plants to develop improved varieties. The comment also stated that uses of plants in speculative manners should not be permitted. *Response:* By statute, a patent provides the patentee with the right to exclude others from, *inter alia,* making and using the claimed invention, although a limited research exemption exists. *See* 35 U.S.C. 163, 271(a), (e). These statutory provisions are not subject to revision by the USPTO and are not affected by these Guidelines. Where a plant is claimed in a utility patent application, compliance with the statutory requirements for utility under 35 U.S.C. 101 only requires that a claimed invention be supported by at least one specific, substantial and credible utility. It is somewhat rare for academic researchers to be sued by commercial patent owners for patent infringement. Most inventions are made available to academic researchers on very favorable licensing terms, which enable them to continue their research.

(17) *Comment:* Two comments suggested that although the USPTO has made a step in the right direction in raising the bar in the Utility Guidelines, there is still a need to apply stricter standards for utility. *Response:* The USPTO is bound by 35 U.S.C. 101 and the case law interpreting § 101. The Guidelines reflect the USPTO's understanding of § 101.

(18) *Comment:* Several comments addressed specific concerns about the examiner training materials. *Response:* The comments received with respect to the training materials will be taken under advisement as the Office revises the training materials. Except for comments with regard to whether sequence homology is sufficient to demonstrate a specific and substantial credible utility, specific concerns about the training materials will not be addressed herein as they will not impact the language of the guidelines.

(19) *Comment:* Several comments suggested that the use of computer-based analysis of nucleic acids to assign a function to a given nucleic acid based upon homology to prior art nucleic acids found in databases is highly unpredictable and cannot form a basis for an assignment of function to a putatively encoded protein. These comments also indicate that even in instances where a general functional assignment may be reasonable, the assignment does not provide information regarding the actual biological activity of an encoded protein and therefore patent claims drawn to such nucleic acids should be limited to method of use claims that are explicitly supported by the as-filed specification(s). These comments also state that if homology-based utilities are acceptable, then the nucleic acids, and proteins encoded thereby, should be considered as obvious over the prior art nucleic acids. On the other hand, one comment stated that homology is a standard, art-accepted basis for predicting utility, while another comment stated that any level of homology to a protein with known utility should be accepted as indicative of utility. *Response:* The suggestions to adopt a *per se* rule rejecting homology-based assertions of utility are not adopted. An applicant is entitled to a patent to the subject matter claimed unless statutory requirements are not met (35 U.S.C. 101, 102, 103, 112). When the USPTO denies a patent, the Office must set forth at least a *prima facie* case as to why an applicant has not met the statutory requirements. The inquiries involved in assessing utility are fact dependent, and the determinations must be made on the basis of scientific evidence. Reliance on the commenters' *per se* rule, rather than a fact dependent inquiry, is impermissible because the commenters provide no scientific evidence that homology-based assertions of utility are inherently unbelievable or involve implausible scientific principles. *See, e.g., In re Brana,* 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (rejection of claims improper where claims did ''not suggest an inherently unbelievable undertaking or involve implausible scientific principles' and where ''prior art * * * discloses structurally similar compounds to those claimed by the applicants which have been proven * * * to be effective'').

A patent examiner must accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. The examiner's decision must be supported by a preponderance of all the evidence of record. *In re Oetiker,* 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion. ''[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient.'' *Fujikawa* v. *Wattanasin,* 93 F.3d 1559, 1565, 39 USPQ2d 1895, 1900 (Fed. Cir. 1996). The Office will take into account both the nature and degree of the homology.

When a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein. If the preponderance of the evidence of record, or of sound scientific reasoning, casts doubt upon such an asserted utility, the examiner should reject the claim for lack of utility under 35 U.S.C. 101. For example, where a class of proteins is defined by common structural features, but evidence shows that the members of the class do not share a specific, substantial functional attribute or utility, despite having structural features in common, membership in the class may not impute a specific, substantial, and credible utility to a new member of the class. When there is a reason to doubt the functional protein assignment, the utility examination may turn to whether or not the asserted protein encoded by a claimed nucleic acid has a well-established use. If there is a well-established utility for the protein and the claimed nucleic acid, the claim would meet the requirements for utility under 35 U.S.C. 101. If not, the burden shifts to the applicant to provide evidence supporting a well-established utility. There is no *per se* rule regarding homology, and each application must be judged on its own merits.

The comment indicating that if a homology-based utility could meet the requirements set forth under 35 U.S.C. 101, then the invention would have been obvious, is not adopted. Assessing nonobviousness under 35 U.S.C. 103 is separate from analyzing the utility requirements under 35 U.S.C. 101. When a claim to a nucleic acid supported by a homology-based utility meets the utility requirement of section 101, it does not follow that the claimed nucleic acid would have been *prima facie* obvious over the nucleic acids to which it is homologous. ''[S]ection 103 requires a fact-intensive comparison of the [claim] with the prior art rather than the mechanical application of one or another *per se* rule.'' *In re Ochiai,* 71 F.3d 1565, 1571, 37 USPQ2d 1127, 1132 (Fed. Cir. 1995). Nonobviousness must be determined according to the analysis

in *Graham* v. *John Deere,* 383 U.S. 1, 148 USPQ 459 (1966). *See also, In re Dillon,* 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc) (''structural similarity between claimed and prior art subject matter, * * * *where the prior art gives reason or motivation to make the claimed compositions,* creates a prima facie case of obviousness'') (emphasis added). Where ''the prior art teaches a specific, structurally-definable compound [] the question becomes whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention.'' *In re Deuel,* 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995).

(20) *Comment:* Several comments indicated that in situations where a well-established utility is relied upon for compliance with 35 U.S.C. 101, the record should reflect what that utility is. One comment stated that the record should reflect whether the examiner accepted an asserted utility or relied upon a well-established utility after dismissing all asserted utilities. Another comment stated that when the examiner relies on a well-established utility not explicitly asserted by the applicant, the written record should clearly identify this utility and the rationale for considering it specific and substantial. *Response:* The comments are not adopted. Only one specific, substantial and credible utility is required to satisfy the statutory requirement. Where one or more well-established utilities would have been readily apparent to those of skill in the art at the time of the invention, an applicant may rely on any one of those utilities without prejudice. The record of any issued patent typically reflects consideration of a number of references in the prior art that the applicant or the examiner considered material to the claimed invention. These references often indicate uses for related inventions, and any patents listed typically disclose utilities for related inventions. Thus, even when the examiner does not identify a well-established utility, the record as a whole will likely disclose readily apparent utilities. Just as the examiner without comment may accept a properly asserted utility, there is no need for an examiner to comment on the existence of a well-established utility. However, the Guidelines have been revised to clarify that a well-established utility is a specific, substantial, and credible utility that must be readily apparent to one skilled in the art. Most often, the closest prior art cited and applied in the course of examining the application will demonstrate a well-established utility for the invention.

(21) *Comment:* Several comments stated that the Guidelines erroneously burden the examiner with proving that a person of skill in the art would not be aware of a well-established utility. One comment states that this requires the examiner to prove a negative. Another comment states that the Guidelines should direct examiners that if a specific utility has not been disclosed, the applicant should be required to identify a specific utility. *Response:* The comments have been adopted in part. The Guidelines have been revised to indicate that where the applicant has not asserted a specific, substantial, and credible utility, and the examiner does not perceive a well-established utility, a rejection under § 101 should be entered. That is, if a well-established utility is not readily apparent and an invention is not otherwise supported by an asserted specific, substantial, and credible utility, the burden will be shifted to applicant to show either that the specification discloses an adequate utility, or to show that a well-established utility exists for the claimed invention. Again, most often the search of the closest prior art will reveal whether there is a well-established utility for the claimed invention.

(22) *Comment:* Several comments suggested that further clarification was required with regard to the examiner's determination that there is an adequate nexus between a showing supporting a well-established utility and the application as filed. The comments indicated that the meaning of this ''nexus'' was unclear. *Response:* The Guidelines have been modified to reflect that evidence provided by an applicant is to be analyzed with regard to a concordance between the showing and the full scope and content of the claimed invention as disclosed in the application as filed. In situations where the showing provides adequate evidence that the claim is supported by at least one asserted specific, substantial, and credible or well-established utility, the rejections under 35 U.S.C. 101 and 112, first paragraph, will be withdrawn. However, the examiner is instructed to consider whether or not the specification, in light of applicant's showing, is enabled for the use of the full scope of the claimed invention. Many times prior patents and printed publications provided by applicant will clearly demonstrate that a well-established utility exists.

(23) *Comment:* One comment states that the Office is using an improper standard in assessing ''specific'' utility. According to the comment, a distinction between ''specific'' and ''general'' utilities is an overreaching interpretation of the specificity requirement in the case law because ''unique'' or ''particular'' utilities have never been required by the law. The comment states that the specificity requirement concerns sufficiency of disclosure, *i.e.,* teaching how to make and use a claimed invention, not the utility requirement. The comment states that the specificity requirement is to be distinguished from the ''substantial'' utility requirement, and that the *Brenner* v. *Manson* decision concerned only a ''substantial'' utility issue, not specificity. *Response:* The comment is not adopted. The disclosure of only a general utility rather than a particular utility is insufficient to meet statutory requirements. Although the specificity requirement is relevant to § 112, it is not severable from the utility requirement.

> [S]urely Congress intended § 112 to presuppose *full satisfaction* of the requirements of § 101. Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention. As this court stated in *Diederich,* quoting with approval from the decision of the board:
>
> 'We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.' As the Supreme Court said in Brenner v. Manson:
>
> '* * * a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.'
>
> *In re Kirk,* 376 F.2d 936, 942, 153 USPQ 48, 53 (CCPA 1967) (affirming rejections under §§ 101 and 112) (emphasis in original).

II. Guidelines for Examination of Applications for Compliance With the Utility Requirement

A. Introduction

The following Guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of 35 U.S.C. 101 and 112. These Guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility

requirement. The Guidelines do not alter the substantive requirements of 35 U.S.C. 101 and 112, nor are they designed to obviate the examiner's review of applications for compliance with all other statutory requirements for patentability. The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

B. Examination Guidelines for the Utility Requirement

Office personnel are to adhere to the following procedures when reviewing patent applications for compliance with the ''useful invention'' (''utility'') requirement of 35 U.S.C. 101 and 112, first paragraph.

1. Read the claims and the supporting written description.

(a) Determine what the applicant has claimed, noting any specific embodiments of the invention.

(b) Ensure that the claims define statutory subject matter (*i.e.,* a process, machine, manufacture, composition of matter, or improvement thereof).

(c) If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (*e.g.,* properties or applications of a product or process), and (2) the utility is specific, substantial, and credible.

2. Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible:

(a) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (*i.e.,* it has a ''specific and substantial utility'') and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.

(1) A claimed invention must have a specific and substantial utility. This requirement excludes ''throw-away,'' ''insubstantial,'' or ''nonspecific'' utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. 101.

(2) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (*e.g.,* test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

(b) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a readily apparent well-established utility, reject the claim(s) under § 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under § 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The § 112, first paragraph, rejection imposed in conjunction with a § 101 rejection should incorporate by reference the grounds of the corresponding § 101 rejection.

(c) If the applicant has not asserted any specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, impose a rejection under § 101, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under § 112, first paragraph, on the basis that the applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility. The §§ 101 and 112 rejections shift the burden of coming forward with evidence to the applicant to:

(1) Explicitly identify a specific and substantial utility for the claimed invention; and

(2) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well established at the time of filing. The examiner should review any subsequently submitted evidence of utility using the criteria outlined above. The examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.

3. Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (*e.g.,* scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

(a) Where the asserted utility is not specific or substantial, a *prima facie* showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The *prima facie* showing must contain the following elements:

(1) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;

(2) Support for factual findings relied upon in reaching this conclusion; and

(3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(b) Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention.

The *prima facie* showing must contain the following elements:

(1) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;

(2) Support for factual findings relied upon in reaching this conclusion; and

(3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(c) Where no specific and substantial utility is disclosed or is well-established, a *prima facie* showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well-established utility.

4. A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to

an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

Once a *prima facie* showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a patent or a printed publication that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a *prima facie* rejection based on lack of utility under § 101, withdraw the § 101 rejection and the corresponding rejection imposed under § 112, first paragraph.

Dated: December 29, 2000.

Q. Todd Dickinson,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. 991027288–0264–02]

RIN 0651–AB10

Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, ''Written Description'' Requirement

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: These Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the ''written description'' requirement of 35 U.S.C. 112, ¶ 1. These Guidelines supersede the ''Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 'Written Description' Requirement'' that were published in the **Federal Register** at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. These Guidelines reflect the current understanding of the USPTO regarding the written description requirement of 35 U.S.C. 112, ¶ 1, and are applicable to all technologies.

DATES: The Guidelines are effective as of January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Stephen Walsh by telephone at (703) 305–9035, by facsimile at (703) 305–9373, by mail to his attention addressed to United States Patent and Trademark Office, Box 8, Washington, DC 20231, or by electronic mail at ''stephen.walsh@uspto.gov''; or Linda Therkorn by telephone at (703) 305–8800, by facsimile at (703) 305–8825, by mail addressed to Box Comments, Commissioner for Patents, Washington, DC 20231, or by electronic mail at ''linda.therkorn@uspto.gov.''

SUPPLEMENTARY INFORMATION: As of the publication date of this notice, these Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the ''written description'' requirement of 35 U.S.C. 112, ¶ 1. Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

Discussion of Public Comments

Comments were received from 48 individuals and 18 organizations in response to the request for comments on the ''Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 'Written Description' Requirement'' published in the **Federal Register** at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. The written comments have been carefully considered.

Overview of Comments

The majority of comments favored issuance of final written description guidelines with minor revisions. Comments pertaining to the written description guidelines are addressed in detail below. A few comments addressed particular concerns with respect to the associated examiner training materials that are available for public inspection at the USPTO web site (www.uspto.gov). Such comments will be taken under advisement in the revision of the training materials; consequently, these comments are not specifically addressed below as they do not impact the content of the Guidelines. Several comments raised issues pertaining to the patentability of ESTs, genes, or genomic inventions with respect to subject matter eligibility (35 U.S.C. 101), novelty (35 U.S.C. 102), or obviousness (35 U.S.C. 103). As these comments do not pertain to the written description requirement under 35 U.S.C. 112, they have not been addressed. However, the aforementioned comments are fully addressed in the ''Discussion of Public Comments'' in the ''Utility Examination Guidelines'' Final Notice, which will be published at or about the same time as the present Guidelines.

Responses to Specific Comments

(1) *Comment:* One comment stated that the Guidelines instruct the patent examiner to determine the correspondence between what applicant has described as the essential identifying characteristic features of the invention and what applicant has claimed, and that such analysis will lead to error. According to the comment, the examiner may decide what applicant should have claimed and reject the claim for failure to claim what the examiner considers to be the invention. Another comment suggested that the Guidelines should clarify what is meant by ''essential features of the invention.'' Another comment suggested that what applicant has identified as the ''essential distinguishing characteristics'' of the invention should be understood in terms of *Fiers* v. *Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993) (''Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name,

formula, or definitive chemical or physical properties.'').

Response: The suggestions have been adopted in part. The purpose of the written description analysis is to confirm that applicant had possession of what is claimed. The Guidelines have been modified to instruct the examiners to compare the scope of the invention claimed with the scope of what applicant has defined in the description of the invention. That is, the Guidelines instruct the examiner to look for consistency between a claim and what provides adequate factual support for the claim as judged by one of ordinary skill in the art from reading the corresponding written description.

(2) *Comment:* Two comments urge that *Regents of the University of California* v. *Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), is bad law and should not be followed by the USPTO because it conflicts with binding precedent, such as *Vas-Cath* v. *Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991). *Response:* The final Guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit. *Eli Lilly* is a precedential decision by the Court that has exclusive jurisdiction over appeals involving patent law. Accordingly, the USPTO must follow *Eli Lilly*. Furthermore, the USPTO does not view *Eli Lilly* as conflicting with *Vas-Cath*. *Vas-Cath* explains that the purpose of the written description requirement is to ensure that the applicant has conveyed to those of skill in the art that he or she was in possession of the claimed invention at the time of filing. *Vas-Cath*, 935 F.2d at 1563–64, 19 USPQ2d at 1117. *Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because ''it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.'' *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus, *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed.

(3) *Comment:* Several comments urged that the Guidelines do not recognize the inconsistency between the original claim doctrine and the written description requirement as set out in *Fiers* and *Eli Lilly*. On the other hand, another comment asserts that there is no strong presumption that an originally filed claim constitutes an adequate written description of the claimed subject matter. Several comments indicate that *in haec verba* support should be sufficient to comply with the written description requirement. Two comments urge that the concept of constructive reduction to practice upon filing of an application has been ignored. *Response:* As noted above, the USPTO does not find *Fiers* and *Eli Lilly* to be in conflict with binding precedent. An original claim may provide written description for itself, but it still must be an *adequate* written description which establishes that the inventor was in possession of the invention. The ''original claim doctrine'' is founded on cases which stand for the proposition that originally filed claims are part of the written description of an application as filed, and thus subject matter which is present only in originally filed claims need not find independent support in the specification. *See, e.g., In re Koller*, 613 F.2d 819, 824, 204 USPQ 702, 706 (CCPA 1980) (later added claims of similar scope and wording were adequately described by original claims); *In re Gardner*, 480 F.2d 879, 880, 178 USPQ 149, 149 (CCPA 1973) (''Under these circumstances, we consider the original claim in itself adequate 'written description' of the claimed invention. It was equally a 'written description' * * * whether located among the original claims or in the descriptive part of the specification.''). However, as noted in the preceding comment, *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed. When the name of a novel chemical compound does not convey sufficient structural information about the compound to identify the compound, merely reciting the name is not enough to show that the inventor had possession of the compound at the time the name was written. The Guidelines indicate that there is a ''strong presumption'' that an adequate written description of the claimed invention is present when the application is filed, consistent with *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) (''we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.''). In most cases, the statement that ''an originally filed claim is its own written description,'' is borne out because the claim language conveys to others of skill in the art that the applicant was ''in possession'' of what is claimed. The Guidelines emphasize that the burden of proof is on the examiner to establish that a description as filed is not adequate and require the examiner to introduce sufficient evidence or technical reasoning to shift the burden of going forward with contrary evidence to the applicant.

(4) *Comment:* One comment stated that the Guidelines change the substance of the written description requirement to require some level of enablement. The comment stated that the *Eli Lilly* case should not be followed because its change in the quality of the description required is in conflict with precedent. Another comment suggested that to comply with the written description requirement, the description must both (i) demonstrate possession of the claimed invention by the applicant; and (ii) put the public in possession of the claimed invention. *Response:* As noted in the comment above, the USPTO is bound by the Federal Circuit's decision in *Eli Lilly*. The Guidelines have been revised to clarify that an applicant must provide a description of the claimed invention which shows that applicant was in possession of the claimed invention. The suggestion to emphasize that the written description requirement must put the public in possession of the invention has not been adopted because it removes much of the distinction between the written description requirement and the enablement requirement. Although the two concepts are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention.

(5) *Comment:* One comment suggested that the Guidelines should provide examples of situations in which the written description requirement was met but the enablement requirement was not, and vice versa. Another comment stated that examiners often use enablement language in making

written description rejections. *Response:* The enablement and written description requirements are not coextensive and, therefore, situations will arise in which one requirement is met but the other is not. Federal Circuit case law demonstrates many circumstances where enablement or written description issues, but not both, were before the Court. These Guidelines are intended to clarify for the examining corps the criteria needed to satisfy the written description requirement. For examples applying these Guidelines to hypothetical fact situations, see the ''Synopsis of Application of Written Description Guidelines'' (examiner training materials available on-line at *http://www.uspto.gov/web/menu/written.pdf).* These examples, as well as the examination form paragraphs and instructions on their proper use, provide the appropriate language examiners should use in making written description rejections.

(6) *Comment:* One comment disagreed with the statement in an endnote that ''the fact that a great deal more than just a process is necessary to render a product invention obvious means that a great deal more than just a process is necessary to provide written description for a product invention.'' The comment indicated that the statement is overly broad and inconsistent with the ''strong presumption that an adequate written description of the claimed invention is present when the application is filed.'' As an extreme case, for example, for product-by-process claims, nothing else would be needed to provide the written description of the product. *Response:* The endnote has been clarified and is now more narrowly drawn. However, there is no *per se* rule that disclosure of a process is sufficient to adequately describe the products produced by the process. In fact, *Fiers* v. *Revel* and *Eli Lilly* involved special circumstances where the disclosure of a process of making and the function of the product alone did not provide an adequate written description for product claims. Even when a product is claimed in a product-by-process format, the adequacy of the written description of the process to support product claims must be evaluated on a case-by-case basis.

(7) *Comment:* Several comments urge that actual reduction to practice, as a method of satisfying the written description requirement by demonstrating possession, has been over-emphasized. *Response:* The Guidelines have been clarified to state that describing an actual reduction to practice is one of a number of ways to show possession of the invention. Description of an actual reduction to practice offers an important ''safe haven'' that applies to all applications and is just one of several ways by which an applicant may demonstrate possession of the claimed invention. Actual reduction to practice may be crucial in the relatively rare instances where the level of knowledge and level of skill are such that those of skill in the art cannot describe a composition structurally, or specify a process of making a composition by naming components and combining steps, in such a way as to distinguish the composition with particularity from all others. Thus, the emphasis on actual reduction to practice is appropriate in those cases where the inventor cannot provide an adequate description of what the composition is, and a definition by function is insufficient to define a composition ''because it is only an indication of what the [composition] does, rather than what it is.'' *Eli Lilly,* 119 F.3d at 1568, 43 USPQ at 1406. *See also Amgen Inc.* v. *Chugai Pharmaceutical Co.,* 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

(8) *Comment:* One comment asserts that the citation to *Pfaff* v. *Wells Electronics, Inc.,* 525 U.S. 55, 48 USPQ2d 1641 (1998) is inappropriate and should be deleted because *Pfaff* is concerned with § 102(b) on-sale bar, not written description. Another comment suggested that the Guidelines should provide an explanation of how the ''ready for patenting'' concept of *Pfaff* should be used in determining compliance with the written description requirement. *Response:* The Guidelines state the general principle that actual reduction to practice is not required to show possession of, or to adequately describe, a claimed invention (although, as noted in the previous comment, an actual reduction to practice is crucial in relatively rare instances). An alternative is to show that the invention described was ''ready for patenting'' as set out in *Pfaff.* For example, a *description* of activities that demonstrates the invention was ''ready for patenting'' satisfies the written description requirement. As *Wertheim* indicates, ''how the specification accomplishes this is not material.'' 541 F.2d at 262, 191 USPQ at 96.

(9) *Comment:* One comment stated that the written description of a claimed DNA should be required to include the complete sequence of the DNA and claims should be limited to the DNA sequence disclosed. *Response:* Describing the complete chemical structure, *i.e.,* the DNA sequence, of a claimed DNA is one method of satisfying the written description requirement, but it is not the only method. *See Eli Lilly,* 119 F.3d at 1566, 43 USPQ2d at 1404 (''An adequate written description of a DNA * * * requires a precise definition, *such as* by structure, formula, chemical name, or physical properties.'' (emphasis added, internal quote omitted)). Therefore, there is no basis for a *per se* rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed.

(10) *Comment:* One comment stated that it is difficult to envision how one could provide a description of sufficient identifying characteristics of the invention without physical possession of a species of the invention, and thus this manner of showing possession should be considered as a way to show actual reduction to practice. *Response:* This suggestion has not been adopted. The three ways of demonstrating possession as set forth in the Guidelines are merely exemplary and are not mutually exclusive. While there are some cases where a description of sufficient relevant identifying characteristics will evidence an actual reduction to practice, there are other cases where it will not. *See, e.g., Ralston Purina Co.* v. *Far-Mar-Co, Inc.,* 772 F.2d 1570, 1576, 227 USPQ 177, 180 (Fed. Cir. 1985) (disclosure taken with the knowledge of those skilled in the art may be sufficient support for claims).

(11) *Comment:* One comment stated that the Guidelines should be revised to indicate that the test of disclosure of sufficiently detailed drawings should be expanded to include structural claiming of chemical entities. *Response:* The suggestion has been adopted.

(12) *Comment:* One comment stated that the Guidelines should reflect that an inventor is in possession of the invention when the inventor demonstrably has at least a complete conception thereof, and that factors and attributes which provide proof of written description should include evidence typically provided to prove a complete conception. *Response:* The suggestion has not been adopted because the conception analysis typically involves documentary evidence in addition to the description of the invention in the application as filed. However, it is acknowledged that if evidence typically provided to prove a complete conception is present in the specification as filed, it would be sufficient to show possession. The Federal Circuit has stated ''[t]he conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot prove possession

of the complete mental picture of the invention.'' *Burroughs Wellcome Co.* v. *Barr Labs., Inc.,* 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994). As further noted by the Federal Circuit, in order to prove conception, ''a party must show possession of every feature recited in the count, and that every limitation of the count must have been known to the inventor at the time of the alleged conception.'' *Coleman* v. *Dines,* 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985).

(13) *Comment:* One comment indicated that a ''possession'' test does not appear in Title 35 of the U.S. Code and is not clearly stated by the Federal Circuit. Therefore, it is recommended that patent examiners be directed to use existing judicial precedent to make rejections of claims unsupported by a statutory written description requirement. *Response:* While the Federal Circuit has not specifically laid out a ''possession'' test, the Court has clearly indicated that possession is a cornerstone of the written description inquiry. *See, e.g., Vas-Cath, Inc.* v. *Mahurkar,* 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); *see also Purdue Pharma L.P.* v. *Faulding Inc.,* 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (''[o]ne skilled in the art, reading the disclosure, must immediately discern the limitation at issue in the claims'') (internal quote omitted). The possession test as set forth in the Guidelines is extrapolated from case law in a wide variety of technologies and is not intended to be limiting. Any rejections made by examiners will be made under 35 U.S.C. 112, ¶1, with supporting rationale. Final rejections are appealable if applicant disagrees and follows the required procedures to appeal.

(14) *Comment:* Two comments indicated that if the amino acid sequence for a polypeptide whose utility has been identified is described, then the question of possession of a class of nucleotides encoding that polypeptide can be addressed as a relatively routine matter using the understanding of the genetic code, and that the endnote addressing this issue should be revised. *Response:* The suggestion of these comments has been incorporated in the Guidelines and will be reflected in the training materials. However, based upon *In re Bell,* 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird,* 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994), this does not mean that applicant was in possession of any particular species of the broad genus.

(15) *Comment:* One comment disagreed with an endnote which stated that a laundry list disclosure of moieties does not constitute a written description of every species in a genus. Specifically, the comment indicates that if the existence of a functional genus is adequately described in the specification, a laundry list of the species within that genus must satisfy the written description requirement. *Response:* The suggestion to revise the endnote will not be adopted. A lack of adequate written description problem arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosure. This was aptly demonstrated in *In re Bell* and *In re Baird* where possession of a large genus did not put a person of ordinary skill in the art in possession of any particular species. *See also Purdue Pharma,* 230 F.3d at 1328, 56 USPQ2d at 1487 (because the original specification did not disclose the later claimed concentration ratio was a part of the invention, the inventors cannot argue that they are merely narrowing a broad invention).

(16) *Comment:* One comment suggested that in the majority of cases, a single species will support a generic claim, and that the Guidelines should emphasize this point. *Response:* The suggestion has been adopted to a limited degree. The Guidelines now indicate that a single species may, in some instances, provide an adequate written description of a generic claim when the description of the species would evidence to one of ordinary skill in the art that the invention includes the genus. Note, however, *Tronzo* v. *Biomet, Inc.,* 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998), where the species in the parent application was held not to provide written description support for the genus in the child application.

(17) *Comment:* One comment asserted that the Guidelines should focus on the compliance of the claims, not the specification, with the written description requirement. *Response:* This suggestion will not be adopted. ''The specification shall contain a written description of the invention.'' 35 U.S.C. 112. The claims are part of the specification. *Id.,* ¶ 2. If an adequate description is provided, it will suffice ''whether located among the original claims or in the descriptive part of the specification.'' *In re Gardner,* 480 F.2d 879, 880, 178 USPQ 149 (CCPA 1973). The entire disclosure, including the specification, drawings, and claims, must be considered.

(18) *Comment:* One comment asserted that the Guidelines confuse ''new matter,'' 35 U.S.C. 132, with the written description requirement, and that the same standard for written description should be applied to both original claims and new or amended claims. *Response:* The Guidelines indicate that for both original and amended claims, the inquiry is whether one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention at the time the application was filed.

(19) *Comment:* One comment suggested that the second paragraph of the section pertaining to determining what the claim as a whole covers should be deleted because it relates more to compliance with § 112, second paragraph, than with the written description requirement. *Response:* This suggestion will not be adopted. The claims must be construed and all issues as to the scope and meaning of the claim must be explored during the inquiry into whether the written description requirement has been met. The concept of treating the claim as a whole is applicable to all criteria for patentability.

(20) *Comment:* One comment suggested a different order for the general analysis for determining compliance with the written description requirement, starting with reading the claim, then the specification, and then determining whether the disclosure demonstrates possession by the applicant. *Response:* This suggestion will not be adopted. The claims must be construed as broadly as reasonable in light of the specification and the knowledge in the art. *See In re Morris,* 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Then the disclosure must be evaluated to determine whether it adequately describes the claimed invention, i.e., whether it conveys to a person having ordinary skill in the art that the applicant had possession of what he or she now claims.

(21) *Comment:* Several comments suggested that the Guidelines are unclear with regard to how the examiner should treat the transitional phrase ''consisting essentially of.'' The comments also suggested that the endnote that explains ''consisting essentially of'' does not make clear how the use of this intermediate transitional language affects the scope of the claim. Several comments stated that the USPTO does not have legal authority to treat claims reciting this language as open (equivalent to ''comprising''). Another comment suggested that the phrase ''clear indication in the specification'' be replaced with ''explicit or implicit indication.'' *Response:* The transitional phrase ''consisting essentially of'' ''excludes

ingredients that would 'materially affect the basic and novel characteristics' of the claimed composition.'' *Atlas Powder Co.* v. *E.I. DuPont de Nemours & Co.,* 750 F.2d 1569, 1574, 224 USPQ 409, 412 (Fed. Cir. 1984). The basic and novel characteristics of the claimed invention are limited by the balance of the claim. *In re Janakirama-Rao,* 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963). However, during prosecution claims must be read broadly, consistent with the specification. *In re Morris,* 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Thus, *for purposes of searching for and applying prior art in a rejection under 35 U.S.C. 102 or 103,* if the specification or the claims do not define the ''basic and novel'' properties of the claimed subject matter (or if such properties are in dispute), the broadest reasonable interpretation consistent with the specification is that the basic and novel characteristics are merely the presence of the recited limitations. *See, e.g., Janakirama-Rao,* 317 F.2d at 954, 137 USPQ at 895–96. This does not indicate that the intermediate transitional language is never given weight. Applicants may amend the claims to avoid the rejections or seek to establish that the specification provides definitions of terms in the claims that define the basic and novel characteristics of the claimed invention which distinguish the claimed invention from the prior art. When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte,* 337 F.2d 870, 143 USPQ 256 (CCPA 1964). The language used in the Guidelines is consistent with *PPG Industries Inc.* v. *Guardian Industries Corp.,* 156 F.3d 1351, 1355, 48 USPQ2d 1351, 1355 (Fed. Cir. 1998) (''PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics.'').

(22) *Comment:* One comment stated that the written description should ''disclose the invention,'' including why the invention works and how it was developed. *Response:* This suggestion has not been adopted. An inventor does not need to know how or why the invention works in order to obtain a patent. *Newman* v. *Quigg,* 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989). To satisfy the enablement requirement of 35 U.S.C. 112, ¶1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement of 35 U.S.C. 112, ¶ 1, the description must show that the applicant was in possession of the claimed invention at the time of filing. There is no statutory basis to require disclosure of why an invention works or how it was developed. ''Patentability shall not be negatived by the manner in which the invention was made.'' 35 U.S.C. 103(a).

(23) *Comment:* One comment recommended that the phrases ''emerging and unpredictable technologies'' and ''unpredictable art'' be replaced with the phrase—inventions characterized by factors which are not reasonably predictable in terms of the ordinary skill in the art—. *Response:* The suggestion is adopted in part and the recommended phrase has been added as an alternative.

(24) *Comment:* One comment recommended that the phrase ''conventional in the art'' be replaced with—part of the knowledge of one of ordinary skill in the art—. *Response:* The suggestion is adopted in part and the recommended phrase has been added as an alternative. The standard of ''conventional in the art'' is supported by case law holding that a patent specification ''need not teach, and preferably omits, what is well known in the art.'' *See Spectra-Physics, Inc.* v. *Coherent, Inc.,* 827 F.2d 1524, 1534, 3 USPQ2d 1737, 1743 (Fed. Cir. 1987); *Hybritech Inc.* v. *Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). *See also Atmel Corp.* v. *Information Storage Devices, Inc.,* 198 F.3d 1374, 1382, 53 USPQ2d 1225, 1231 (Fed. Cir. 1999).

(25) *Comment:* One comment recommended that the Guidelines be amended to state that the appropriate skill level for determining possession of the claimed invention is that of a person of *ordinary* skill in the art. *Response:* The comment has not been adopted. The statutory language itself indicates that compliance with the requirements of 35 U.S.C. 112, ¶1, is judged from the standard of ''any person skilled in the art.'' It is noted, however, that the phrases ''one of skill in the art'' and ''one of ordinary skill in the art'' appear to be synonymous. *See, e.g., Union Oil Co.* v. *Atlantic Richfield Co.,* 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) (''The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow *persons of ordinary skill in the art* to recognize that [he or she] invented what is claimed.' Thus, § 112, ¶ 1, ensures that, as of the filing date, the inventor conveyed with reasonable clarity to *those of skill in the art* that he was in possession of the subject matter of the claims.'' (citations omitted, emphasis added)).

(26) *Comment:* One comment stated that an endnote misstates the relevant law in stating that, to show inherent written descriptive support for a claim limitation, the inherent disclosure must be such as would be recognized by a person of ordinary skill in the art. The comment recommended that the endnote be amended to delete the reference to recognition by persons of ordinary skill and to cite *Pingree* v. *Hull,* 518 F.2d 624, 186 USPQ 248 (CCPA 1975), rather than *In re Robertson,* 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). *Response:* The comment has not been adopted. Federal Circuit precedent makes clear that an inherent disclosure must be recognized by those of ordinary skill in the art. *See, e.g., Hyatt* v. *Boone,* 146 F.3d 1348, 1354–55, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998) (''[T]he purpose of the description requirement is 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.' * * * Thus, the written description must include all of the limitations of the interference count, or the applicant must show that any absent text is necessarily comprehended in the description provided *and would have been so understood* at the time the patent application was filed.'' (emphasis added)). *See also Reiffin* v. *Microsoft Corp.,* 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000) (The ''application considered as a whole must convey to one of ordinary skill in the art, either explicitly or inherently, that [the inventor] invented the subject matter claimed * * *. See * * * *Continental Can Co. USA* v. *Monsanto Co.,* 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (descriptive matter may be inherently present in a specification if one skilled in the art would necessarily recognize such a disclosure)'').

(27) *Comment:* Several comments pointed out an inconsistency in the **Federal Register** Notice re: the Revised Interim Written Description Guidelines. The inconsistency concerned the treatment of claims directed to an isolated DNA comprising SEQ ID NO:1 wherein SEQ ID NO:1 is an expressed sequence tag. The comments contrasted paragraphs 34 and 35 of the Response to

Public Comments with the statement in the text of the Guidelines that a genus must be supported by a representative number of species (as analyzed in Example 7 of the training materials). *Response:* The USPTO acknowledges that there was an inconsistency. The Office notes that a claim reciting a nucleic acid comprising SEQ ID NO:1 may be subject to a rejection for lack of an adequate written description where particular identifiable species within the scope of the claim lack an adequate written description. The training materials as amended exemplify an appropriate analysis.

(28) *Comment:* One comment stated that the USPTO should respond to the issue of whether the U.S. is meeting its TRIPs obligations. This comment noted that the USPTO did not address an earlier comment regarding the ''Interim Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1, 'Written Description' Requirement,'' 63 FR 32,639, June 15, 1998, which questioned whether the written description requirement is truly different from the enablement requirement, and indicated that such a requirement may be contrary to the TRIPs provisions of the World Trade Organization (Article 27.1). Article 27.1 requires WTO Members to, *inter alia*, make patents available, with limited exceptions, for products and processes in all fields of technology so long as those products and processes are new, involve an inventive step, and are capable of industrial application. The comment further suggested a response. *Response:* TRIPs Article 27 does not address what must be included in a patent application to allow WTO Member officials to determine whether particular inventions meet the standards for patentability established in that Article. TRIPs Article 29, which is more relevant to this comment, states that Members ''shall require'' patent applicants to disclose their invention ''in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.'' If the written description is not clear and complete, the applicant may not have been in possession of the invention. This may support both written description and enablement standards. In addition, Article 29 expressly authorizes Members to require patent applicants to disclose the best method the inventor knows at the time of filing an application for carrying out the invention.

(29) *Comment:* Two comments commended the USPTO for eliminating the Biotechnology Specific Examples in the Revised Interim Written Description Guidelines and providing separate training materials. One comment indicated a need to reconfirm the examples set forth in the Interim Written Description Guidelines published in 1998. *Response:* The current training materials reflect the manner in which the USPTO interprets the Written Description Guidelines.

(30) *Comment:* Several comments addressed specific concerns about the examiner training materials. *Response:* The comments received with respect to the training materials will be taken under advisement as the Office revises the training materials in view of the revisions to the Guidelines. The specific comments will not be addressed herein as they do not impact the language of the Guidelines.

Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, ''Written Description'' Requirement

These ''Written Description Guidelines'' are intended to assist Office personnel in the examination of patent applications for compliance with the written description requirement of 35 U.S.C. 112, ¶ 1. This revision is based on the Office's current understanding of the law and public comments received in response to the USPTO's previous request for public comments on its Revised Interim Written Description Guidelines and is believed to be fully consistent with binding precedent of the U.S. Supreme Court, as well as the U.S. Court of Appeals for the Federal Circuit and its predecessor courts.

This revision does not constitute substantive rulemaking and hence does not have the force and effect of law. It is designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

These Guidelines are intended to form part of the normal examination process. Thus, where Office personnel establish a *prima facie* case of lack of written description for a claim, a thorough review of the prior art and examination on the merits for compliance with the other statutory requirements, including those of 35 U.S.C. 101, 102, 103, and 112, is to be conducted prior to completing an Office action which includes a rejection for lack of written description. Office personnel are to rely on this revision of the Guidelines in the event of any inconsistent treatment of issues involving the written description requirement between these Guidelines and any earlier guidance provided from the Office.

I. General Principles Governing Compliance With the ''Written Description'' Requirement for Applications

The first paragraph of 35 U.S.C. 112 requires that the ''specification shall contain a written description of the invention * * *.'' This requirement is separate and distinct from the enablement requirement.[1] The written description requirement has several policy objectives. ''[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed.'' [2] Another objective is to put the public in possession of what the applicant claims as the invention.[3] The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.[4] An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.[5] Possession may be shown in a variety of ways including description of an actual reduction to practice,[6] or by showing that the invention was ''ready for patenting'' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete,[7] or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.[8] A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently, a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c).[9] Compliance with the written description requirement is a question of

fact which must be resolved on a case-by-case basis.[10]

A. Original Claims

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed.[11] However, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention.[12] The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art.[13] This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function.[14] A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.[15]

B. New or Amended Claims

The proscription against the introduction of new matter in a patent application [16] serves to prevent an applicant from adding information that goes beyond the subject matter originally filed.[17] Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement.[18] While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction.[19] Deposits made after the application filing date cannot be relied upon to support additions to or correction of information in the application as filed.[20]

Under certain circumstances, omission of a limitation can raise an issue regarding whether the inventor had possession of a broader, more generic invention.[21] A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement.[22]

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.[23]

II. Methodology for Determining Adequacy of Written Description

A. Read and Analyze the Specification for Compliance With 35 U.S.C. 112, ¶1

Office personnel should adhere to the following procedures when reviewing patent applications for compliance with the written description requirement of 35 U.S.C. 112, ¶ 1. The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed;[24] however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims.[25] Consequently, rejection of an original claim for lack of written description should be rare. The inquiry into whether the description requirement is met is a question of fact that must be determined on a case-by-case basis.[26]

1. For Each Claim, Determine What the Claim as a Whole Covers

Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description.[27] The entire claim must be considered, including the preamble language [28] and the transitional phrase.[29] The claim as a whole, including all limitations found in the preamble,[30] the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement.[31]

The examiner should evaluate each claim to determine if sufficient structures, acts, or functions are recited to make clear the scope and meaning of the claim, including the weight to be given the preamble.[32] The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, ¶ 1, for lack of adequate written description. Limitations may not, however, be imported into the claims from the specification.

2. Review the Entire Application to Understand How Applicant Provides Support for the Claimed Invention Including Each Element and/or Step

Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention.[33] The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed [34] and should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification.[35]

3. Determine Whether There is Sufficient Written Description to Inform a Skilled Artisan That Applicant was in Possession of the Claimed Invention as a Whole at the Time the Application Was Filed

a. Original claims. Possession may be shown in many ways. For example, possession may be shown, *inter alia,* by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention.[36]

A specification may describe an actual reduction to practice by showing

that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose.[37] Description of an actual reduction to practice of a biological material may be shown by specifically describing a deposit made in accordance with the requirements of 37 CFR 1.801 *et seq*.[38]

An applicant may show possession of an invention by disclosure of drawings [39] or structural chemical formulas[40] that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. The description need only describe in detail that which is new or not conventional.[41] This is equally true whether the claimed invention is directed to a product or a process.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics [42] which provide evidence that applicant was in possession of the claimed invention,[43] *i.e.,* complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.[44] What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.[45] If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.[46]

(1) For each claim drawn to a single embodiment or species: [47]

(a) Determine whether the application describes an actual reduction to practice of the claimed invention.

(b) If the application does not describe an actual reduction to practice, determine whether the invention is complete as evidenced by a reduction to drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

(c) If the application does not describe an actual reduction to practice or reduction to drawings or structural chemical formula as discussed above, determine whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention.

(i) Determine whether the application as filed describes the complete structure (or acts of a process) of the claimed invention as a whole. The complete structure of a species or embodiment typically satisfies the requirement that the description be set forth ''in such full, clear, concise, and exact terms'' to show possession of the claimed invention.[48] If a complete structure is disclosed, the written description requirement is satisfied for that species or embodiment, and a rejection under 35 U.S.C. 112, ¶ 1, for lack of written description must not be made.

(ii) If the application as filed does not disclose the complete structure (or acts of a process) of the claimed invention as a whole, determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention.[49]

Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.[50] Patents and printed publications in the art should be relied upon to determine whether an art is mature and what the level of knowledge and skill is in the art. In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention.[51] In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession. For example, disclosure of only a method of making the invention and the function may not be sufficient to support a product claim other than a product-by-process claim.[52] Furthermore, disclosure of a partial structure without additional characterization of the product may not be sufficient to evidence possession of the claimed invention.[53]

Any claim to a species that does not meet the test described under at least one of (a), (b), or (c) must be rejected as lacking adequate written description under 35 U.S.C. 112, ¶ 1.

(2) For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see (1)(a), above), reduction to drawings (see (1)(b), above), or by disclosure of relevant, identifying characteristics, *i.e.,* structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see (1)(c), above).[54]

A ''representative number of species'' means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. On the other hand, there may be situations where one species adequately supports a genus.[55] What constitutes a ''representative number'' is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a ''representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus.[56] Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.[57] If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, ¶ 1.

b. New claims, amended claims, or claims asserting entitlement to the benefit of an earlier priority date or filing date under 35 U.S.C. 119, 120, or

365(c). The examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims.[58] However, when filing an amendment an applicant should show support in the original disclosure for new or amended claims.[59] To comply with the written description requirement of 35 U.S.C. 112, ¶ 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly,[60] implicitly,[61] or inherently[62] supported in the originally filed disclosure.[63] Furthermore, each claim must include all elements which applicant has described as essential.[64]

If the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, ¶ 1, as lacking adequate written description, or in the case of a claim for priority under 35 U.S.C. 119, 120, or 365(c), the claim for priority must be denied.

III. Complete Patentability Determination Under All Statutory Requirements and Clearly Communicate Findings, Conclusions, and Their Bases

The above only describes how to determine whether the written description requirement of 35 U.S.C. 112, ¶ 1, is satisfied. Regardless of the outcome of that determination, Office personnel must complete the patentability determination under all the relevant statutory provisions of title 35 of the U.S. Code.

Once Office personnel have concluded analysis of the claimed invention under all the statutory provisions, including 35 U.S.C. 101, 112, 102, and 103, they should review all the proposed rejections and their bases to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions, and reasons which support them. When possible, the Office action should offer helpful suggestions on how to overcome rejections.

A. For Each Claim Lacking Written Description Support, Reject the Claim Under Section 112, ¶ 1, for Lack of Adequate Written Description

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption.[65] The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.[66] In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(1) Identify the claim limitation at issue; and

(2) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. A general allegation of ''unpredictability in the art'' is not a sufficient reason to support a rejection for lack of adequate written description.

When appropriate, suggest amendments to the claims which can be supported by the application's written description, being mindful of the prohibition against the addition of new matter in the claims or description.[67]

B. Upon Reply by Applicant, Again Determine the Patentability of the Claimed Invention, Including Whether the Written Description Requirement Is Satisfied by Reperforming the Analysis Described Above in View of the Whole Record

Upon reply by applicant, before repeating any rejection under 35 U.S.C. 112, ¶ 1, for lack of written description, review the basis for the rejection in view of the record as a whole, including amendments, arguments, and any evidence submitted by applicant. If the whole record now demonstrates that the written description requirement is satisfied, do *not* repeat the rejection in the next Office action. If the record still does not demonstrate that the written description is adequate to support the claim(s), repeat the rejection under 35 U.S.C. 112, ¶ 1, fully respond to applicant's rebuttal arguments, and properly treat any further showings submitted by applicant in the reply. When a rejection is maintained, any affidavits relevant to the 112, ¶ 1, written description requirement,[68] must be thoroughly analyzed and discussed in the next Office action.

Dated: December 29, 2000.

Q. Todd Dickinson,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

Endnotes

[1] *See, e.g., Vas-Cath, Inc.* v. *Mahurkar,* 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991).

[2] *In re Barker,* 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977).

[3] *See Regents of the University of California* v. *Eli Lilly,* 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied,* 523 U.S. 1089 (1998).

[4] *See, e.g., Vas-Cath, Inc.* v. *Mahurkar,* 935 F.2d at 1563, 19 USPQ2d at 1116. Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides ''adequate support'' for the claims at issue or whether the material added to the specification incorporates ''new matter'' in violation of 35 U.S.C. 132. The ''written description'' question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the newly added claims corresponding to the count at issue, *i.e.,* whether that party can ''make the claim'' corresponding to the interference count. *See, e.g., Martin* v. *Mayer,* 823 F.2d 500, 503, 3 USPQ2d 1333, 1335 (Fed. Cir. 1987).

In addition, early opinions suggest the Patent and Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however, this viewpoint was rejected. *See In re Koller,* 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); *accord In re Gardner,* 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); *accord In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976) (accord). It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. These early opinions did not address the quality or specificity of particularity that was required in the description, *i.e.,* how much description is enough.

[5] *Lockwood* v. *American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

[6] An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801 *et seq. See also Deposit of Biological Materials for Patent Purposes, Final Rule,* 54 FR 34,864 (August 22, 1989) (''The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. 112, and to provide an antecedent basis for the biological material which either has been or will be deposited before the patent is granted.'' *Id.* at 34,876. ''The description must be sufficient to permit verification that the deposited biological material is in fact that disclosed. Once the

patent issues, the description must be sufficient to aid in the resolution of questions of infringement.'' *Id.* at 34,880.). Such a deposit is not a substitute for a written description of the claimed invention. The written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description. *See, e.g., In re Lundak,* 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). *See also* 54 FR at 34,880 (''As a general rule, the more information that is provided about a particular deposited biological material, the better the examiner will be able to compare the identity and characteristics of the deposited biological material with the prior art.'').

[7] *Pfaff* v. *Wells Electronics, Inc.,* 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1406.

[8] *See Amgen, Inc.* v. *Chugai Pharmaceutical,* 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by ''whatever characteristics sufficiently distinguish it'').

[9] A description requirement issue can arise for original claims (*see, e.g., Eli Lilly,* 119 F.3d 1559, 43 USPQ2d 1398) as well as new or amended claims. Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (*see, e.g., In re Wright,* 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)), whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c) (*see, e.g., Tronzo* v. *Biomet, Inc.,* 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); *Fiers* v. *Revel,* 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); *In re Ziegler,* 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993)), or whether a specification provides support for a claim corresponding to a count in an interference (*see, e.g., Fields* v. *Conover,* 443 F.2d 1386, 170 USPQ 276 (CCPA 1971)).

[10] *Vas-Cath, Inc.* v. *Mahurkar,* 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

[11] *In re Wertheim,* 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) (''we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims'').

[12] See endnote 4.

[13] For example, consider the claim ''A gene comprising SEQ ID NO:1.'' A determination of what the claim as a whole covers may result in a conclusion that specific structures such as a promoter, a coding region, or other elements are included. Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO:1, there may be insufficient description of those specific structures (*e.g.,* promoters, enhancers, coding regions, and other regulatory elements) which are also included.

[14] A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. *Cf. In re Bell,* 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993), and *In re Deuel,* 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995) (holding that a process could not render the product of that process obvious under 35 U.S.C. 103). The Federal Circuit has pointed out that under United States law, a description that does not render a claimed invention obvious cannot sufficiently describe the invention for the purposes of the written description requirement of 35 U.S.C. 112. *Eli Lilly,* 119 F.3d at 1567, 43 USPQ2d at 1405.

Compare Fonar Corp. v. *General Electric Co.,* 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997) (''As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed. * * * Thus, flow charts or source code listings are not a requirement for adequately disclosing the functions of software.'').

[15] *See, e.g., Fujikawa* v. *Wattanasin,* 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a ''laundry list'' disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not ''reasonably lead'' those skilled in the art to any particular species); *In re Ruschig,* 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) (''*If* n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.'') (emphasis in original); *Purdue Pharma L.P.* v. *Faulding Inc.,* 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) (''the specification does not clearly disclose to the skilled artisan that the inventors * * * considered the [] ratio to be part of their invention * * *. There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion'').

[16] 35 U.S.C. §§ 132 and 251. *See also In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). *See* Manual of Patent Examining Procedure (MPEP) §§ 2163.06–2163.07 (7th Ed., Rev. 1, Feb. 2000) for a more detailed discussion of the written description requirement and its relationship to new matter.

[17] The claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985).

[18] *See, e.g., In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).

[19] *In re Oda*, 443 F.2d 1200, 170 USPQ 260 (CCPA 1971). With respect to the correction of sequencing errors in applications disclosing nucleic acid and/or amino acid sequences, it is well known that sequencing errors are a common problem in molecular biology. *See, e.g.*, Peter Richterich, *Estimation of Errors in 'Raw' DNA Sequences: A Validation Study*, 8 Genome Research 251–59 (1998). If an application as filed includes sequence information and references a deposit of the sequenced material made in accordance with the requirements of 37 CFR § 1.801 *et seq.*, amendment may be permissible.

[20] Corrections of minor errors in the sequence may be possible based on the argument that one of skill in the art would have resequenced the deposited material and would have immediately recognized the minor error. Deposits made after the filing date can only be relied upon to provide support for the correction of sequence information if applicant submits a statement in compliance with 37 CFR § 1.804 stating that the biological material which is deposited is a biological material specifically defined in the application as filed.

[21] *See, e.g., Gentry Gallery, Inc.* v. *Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) (claims to a sectional sofa comprising, *inter alia*, a console and a control means were held invalid for failing to satisfy the written description requirement where the claims were broadened by removing the location of the control means.); *Johnson Worldwide Associates* v. *Zebco Corp.*, 175 F.3d 985, 993, 50 USPQ2d 1607, 1613 (Fed. Cir. 1999) (In *Gentry Gallery*, the ''court's determination that the patent disclosure did not support a broad meaning for the disputed claim terms was premised on clear statements in the written description that described the location of a claim element—the 'control means'—as 'the only possible location' and that variations were 'outside the stated purpose of the invention.' *Gentry Gallery*, 134 F.3d at 1479, 45 USPQ2d at 1503. *Gentry Gallery*, then, considers the situation where the patent's disclosure makes crystal clear that a particular (*i.e.*, narrow) understanding of a claim term is an 'essential element of [the inventor's] invention.' ''); *Tronzo* v. *Biomet*, 156 F.3d at 1158–59, 47 USPQ2d at 1833 (Fed. Cir. 1998) (claims to generic cup shape were not entitled to filing date of parent application which disclosed ''conical cup'' in view of the disclosure of the

parent application stating the advantages and importance of the conical shape.).

[22] *See Gentry Gallery*, 134 F.3d at 1480, 45 USPQ2d at 1503; *In re Sus*, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962) (''[O]ne skilled in this art would not be taught by the written description of the invention in the specification that any 'aryl or substituted aryl radical' would be suitable for the purposes of the invention but rather that only *certain aryl radicals* and certain specifically substituted aryl radicals [*i.e.,* aryl azides] would be suitable for such purposes.'') (emphasis in original). A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may also be subject to rejection under 35 U.S.C. 112, ¶ 1, as not enabling, or under 35 U.S.C. 112, ¶ 2. *See In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976); *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); and *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). *See also* MPEP § 2172.01.

[23] *See, e.g., Vas-Cath, Inc.*, 935 F.2d at 1563–64, 19 USPQ2d at 1117.

[24] *Wertheim*, 541 F.2d at 262, 191 USPQ at 96.

[25] *See* MPEP §§ 714.02 and 2163.06 (''Applicant should * * * specifically point out the support for any amendments made to the disclosure.''); and MPEP § 2163.04 (''If applicant amends the claims and points out where and/or how the originally filed disclosure supports the amendment(s), and the examiner finds that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of the filing of the application, the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.'').

[26] *See In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (''Precisely how close [to the claimed invention] the description must come to comply with § 112 must be left to case-by-case development.''); *In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96 (inquiry is primarily factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure).

[27] *See, e.g., In re Morris*, 127 F.3d 1048, 1053–54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

[28] ''Preamble language'' is that language in a claim appearing before the transitional phase, *e.g.*, before ''comprising,'' ''consisting essentially of,'' or ''consisting of.''

[29] The transitional term ''comprising'' (and other comparable terms, *e.g.*, ''containing,'' ''including,'' and ''having'') is ''open-ended—it covers the expressly recited subject matter, alone or in combination with unrecited subject matter. *See, e.g., Genentech, Inc.* v. *Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (' 'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.''); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (''comprising'' leaves the ''claim open for the inclusion of unspecified ingredients even in major amounts''). ''By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format.'' *PPG Industries* v. *Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353–54 (Fed. Cir. 1998). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to ''comprising.'' *See, e.g., PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 (''PPG could have defined the scope of the phrase ''consisting essentially of'' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.''). *See also In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895–96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of ''consisting essentially of,'' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

[30] *See Pac-Tec Inc.* v. *Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention).

[31] An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

[32] *See, e.g., Bell Communications Research, Inc.* v. *Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995) (''[A] claim preamble has the import that the claim as a whole suggests for it.''); *Corning Glass Works* v. *Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application ''to gain an understanding of what the inventors actually invented and intended to encompass by the claim.'').

[33] An element may be critical where those of skill in the art would require it to determine that applicant was in possession of the invention. *Compare Rasmussen*, 650 F.2d at 1215, 211 USPQ at 327 (''one skilled in the art who read Rasmussen's specification would understand that it is unimportant *how* the layers are adhered, so long as they are adhered'') (emphasis in original), *with Amgen, Inc.* v. *Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (''it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it'').

[34] *See, e.g., Wang Labs.* v. *Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993).

[35] *See, e.g., Hybritech, Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379–80, 231 USPQ 81, 90 (Fed. Cir. 1986).

[36] *See, e.g., Purdue Pharma L.P.* v. *Faulding Inc.*, 230 F.3d 1320, ___, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description ''inquiry is a factual one and must be assessed on a case-by-case basis''); *see also Pfaff* v. *Wells Electronics, Inc.*, 55 U.S. at 66, 119 S.Ct. at 311, 48 USPQ2d at 1646 (''The word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete.' It is true that reduction to practice ordinarily provides the best evidence that an invention is complete. But just because reduction to practice is sufficient evidence of completion, it does not follow that proof of reduction to practice is necessary in every case. Indeed, both the facts of the *Telephone Cases* and the facts of this case demonstrate that one can prove that an invention is complete and ready for patenting before it has actually been reduced to practice.'').

[37] *Cooper* v. *Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). *See also UMC Elecs. Co.* v. *United States*, 816 F.2d 647, 652, 2 USPQ2d 1465, 1468 (Fed. Cir. 1987) (''[T]here cannot be a reduction to practice of the invention * * * without a physical embodiment which includes all limitations of the claim.''); *Estee Lauder Inc.* v. *L'Oreal, S.A.*, 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997) (''[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose.''); *Mahurkar* v. *C.R. Bard, Inc.*, 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996) (determining that the invention will work for its intended purpose may require testing depending on the character of the invention and the problem it solves).

[38] 37 CFR 1.804, 1.809. *See also* endnote 6.

[39] *See, e.g., Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118 (''drawings alone may provide a 'written description' of an invention as required by § 112''); *In re Wolfensperger*, 302 F.2d 950, 133 USPQ 537 (CCPA 1962) (the drawings of applicant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co. of America* v. *United States*, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967) (''In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification.'').

[40] *See, e.g., Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (''In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.'').

[41] *See Hybritech* v. *Monoclonal Antibodies*, 802 F.2d at 1384, 231 USPQ at 94; *Fonar Corp.* v. *General Electric Co.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (source code description not required).

[42] For example, the presence of a restriction enzyme map of a gene may be relevant to a statement that the gene has been isolated. One skilled in the art may be able to determine when the gene disclosed is the same as or different from a gene isolated by another by comparing the restriction enzyme map. In contrast, evidence that the gene could be digested with a nuclease would not normally represent a relevant characteristic since any gene would be digested with a nuclease. Similarly, isolation of an mRNA and its expression to produce the protein of interest is strong evidence of possession of an mRNA for the protein.

For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession. For example, unique cleavage by particular enzymes, isoelectric points of fragments, detailed restriction enzyme maps, a comparison of enzymatic activities, or antibody cross-reactivity may be sufficient to show possession of the claimed invention to one of skill in the art. *See Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966 (''written description'' requirement may be satisfied by using ''such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention'').

[43] A definition by function alone ''does not suffice'' to sufficiently describe a coding sequence ''because it is only an indication of what the gene does, rather than what it is.'' *Eli Lilly*, 119 F.3 at 1568, 43 USPQ2d at 1406. *See also Fiers*, 984 F.2d at 1169–71, 25 USPQ2d at 1605–06 (discussing *Amgen Inc.* v. *Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)).

[44] If a claim limitation invokes 35 U.S.C. 112, ¶ 6, it must be interpreted to cover the corresponding structure, materials, or acts in the specification and ''equivalents thereof.'' *See* 35 U.S.C. 112, ¶ 6. *See also B. Braun Medical, Inc.* v. *Abbott Lab.*, 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1899 (Fed. Cir. 1997). In considering whether there is 35 U.S.C. 112, ¶ 1, support for a means- (or step) plus-function claim limitation, the examiner must consider not only the original disclosure contained in the summary and detailed description of the invention portions of the specification, but also the original claims, abstract, and drawings. A means- (or step-) plus-function claim limitation is adequately described under 35 U.S.C. 112, ¶ 1, if: (1) The written description adequately links or associates adequately described particular structure, material, or acts to the function recited in a means- (or step-) plus-function claim limitation; or (2) it is clear based on the facts of the application that one skilled in the art would have known what structure, material, or acts perform the function recited in a means- (or step-) plus-function limitation. Note also: A rejection under 35 U.S.C. 112, ¶ 2, ''cannot stand where there is adequate description in the specification to satisfy 35 U.S.C. 112, first paragraph, regarding means-plus-function recitations that are not, per se, challenged for being unclear.'' *In re Noll*, 545 F.2d 141, 149, 191 USPQ 721, 727 (CCPA 1976). *See Supplemental Examination Guidelines for Determining the Applicability of 35 U.S.C. 112, ¶ 6*, 65 FR 38510, June 21, 2000.

[45] *See Hybritech Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94.

[46] *See, e.g.*, *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin* v. *Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating ''the description need not be in *ipsis verbis* [*i.e.*, ''in the same words''] to be sufficient'').

[47] A claim which is limited to a single disclosed embodiment or species is analyzed as a claim drawn to a single embodiment or species, whereas a claim which encompasses two or more embodiments or species within the scope of the claim is analyzed as a claim drawn to a genus. *See also* MPEP § 806.04(e).

[48] 35 U.S.C. 112, ¶ 1. *Cf. Fields* v. *Conover*, 443 F.2d 1386, 1392, 170 USPQ 276, 280 (CCPA 1971) (finding a lack of written description because the specification lacked the ''full, clear, concise, and exact written description'' which is necessary to support the claimed invention).

[49] For example, if the art has established a strong correlation between structure and function, one skilled in the art would be able to predict with a reasonable degree of confidence the structure of the claimed invention from a recitation of its function. Thus, the written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. In contrast, without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In this latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (written description requirement not satisfied by merely providing ''a result that one might achieve if one made that invention''); *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372–73 (Fed. Cir. 1984) (affirming a rejection for lack of written description because the specification does ''little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate''). *Compare Fonar*, 107 F.3d at 1549, 41 USPQ2d at 1805 (disclosure of software function adequate in that art).

[50] *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

[51] *See, e.g.*, *In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534–35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992) (''One skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification. Thus, an inventor is not required to describe every detail of his invention. An applicant's disclosure obligation varies according to the art to which the invention pertains. Disclosing a microprocessor capable of performing certain functions is sufficient to satisfy the requirement of section 112, first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out.'')

[52] *See, e.g.*, *Fiers* v. *Revel*, 984 F.2d at 1169, 25 USPQ2d at 1605; *Amgen.*, 927 F.2d at 1206, 18 USPQ2d at1021. Where the process has actually been used to produce the product, the written description requirement for a product-by-process claim is clearly satisfied; however, the requirement may not be satisfied where it is not clear that the acts set forth in the specification can be performed, or that the product is produced by that process.

[53] *See, e.g.*, *Amgen*, 927 F.2d at1206, 18 USPQ2d at 1021 (''A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.'') (citations omitted). In such instances the alleged conception fails not merely because the field is unpredictable or because of the general uncertainty surrounding experimental sciences, but because the conception is incomplete due to factual uncertainty that undermines the specificity of the inventor's idea of the invention. *Burroughs Wellcome Co.* v. *Barr Laboratories Inc.*, 40 F.3d 1223, 1229, 32 USPQ2d 1915, 1920 (Fed. Cir. 1994). Reduction to practice in effect provides the only evidence to corroborate conception (and therefore possession) of the invention. *Id.*

[54] *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

[55] *See, e.g.*, *Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326–27 (disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to ''adheringly applying'' because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered); *In re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979) (disclosure of corticosteriod in DMSO sufficient to support claims drawn to a method of using a mixture of a ''physiologically active steroid'' and DMSO because ''use of known chemical compounds in a manner auxiliary

to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description.''); *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973) (the phrase ''air or other gas which is inert to the liquid'' was sufficient to support a claim to ''inert fluid media'' because the description of the properties and functions of the air or other gas segmentizing medium would suggest to a person skilled in the art that appellant's invention includes the use of ''inert fluid'' broadly.). However, in *Tronzo* v. *Biomet*, 156 F.3d at 1159, 47 USPQ2d at1833 (Fed. Cir. 1998), the disclosure of a species in the parent application did not suffice to provide written description support for the genus in the child application.

[56] *See, e.g., Eli Lilly*.

[57] For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. *Cf. In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

[58] *See Wertheim*, 541 F.2d at 263, 191 USPQ at 97 (''[T]he PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.'').

[59] *See* MPEP §§ 714.02 and 2163.06 (''Applicant should * * * specifically point out the support for any amendments made to the disclosure.'').

[60] *See, e.g., In re Wright*, 866 F.2d 422, 425, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989) (Original specification for method of forming images using photosensitive microcapsules which describes removal of microcapsules from surface and warns that capsules not be disturbed prior to formation of image, unequivocally teaches absence of permanently fixed microcapsules and supports amended language of claims requiring that microcapsules be ''not permanently fixed'' to underlying surface, and therefore meets description requirement of 35 U.S.C. 112.).

[61] *See, e.g., In re Robins*, 429 F.2d 452, 456–57, 166 USPQ 552, 555 (CCPA 1970) (''[W]here no explicit description of a generic invention is to be found in the specification * * * mention of representative compounds may provide an implicit description upon which to base generic claim language.''); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads).

[62] *See, e.g., In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950–51 (Fed. Cir. 1999) (''To establish inherency, the extrinsic evidence ''must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'''') (citations omitted).

[63] When an explicit limitation in a claim ''is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.'' *Hyatt* v. *Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998).

[64] *See, e.g., Johnson Worldwide Associates Inc.* v. *Zebco Corp.*, 175 F.3d at 993, 50 USPQ2d at 1613; *Gentry Gallery, Inc.* v. *Berkline Corp.*, 134 F.3d at 1479, 45 USPQ2d at 1503; *Tronzo* v. *Biomet*, 156 F.3d at 1159, 47 USPQ2d at 1833.

[65] *See, e.g., In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

[66] *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

[67] *See Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326.

[68] *See In re Alton*, 76 F.3d 1168, 1176, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996).

[FR Doc. 01–323 Filed 1–4–01; 8:45 am]

BILLING CODE 3510–16–U

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Revision of Currently Approved Information Collection; Comment Request

AGENCY: Corporation for National and Community Service

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter ''Corporation''), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, the Corporation is soliciting comments concerning the proposed revision of its Voucher and Payment Request Form (OMB #3045–0014).

Copies of the forms can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section by March 6, 2001.

ADDRESSES: Send comments to Levon Buller, National Service Trust, Corporation for National and Community Service, 1201 New York Ave., NW., Washington, DC 20525.

FOR FURTHER INFORMATION CONTACT: Levon Buller, (202) 606–5000, ext. 383.

SUPPLEMENTARY INFORMATION: The Corporation is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Background

The Corporation supports programs that provide opportunities for individuals who want to become involved in national service. The service opportunities cover a wide range of activities over varying periods of time. Upon successfully completing an agreed-upon term of service in an approved AmeriCorps program, a national service participant—an AmeriCorps member—receives an ''education award''. This award is an amount of money set aside in the member's name in the National Service Trust Fund. This education award can be used to make payments towards qualified student loan or pay for educational expenses at qualified post-secondary institutions and approved school-to-work opportunities programs. Members have seven years in which to draw against any unused balance.

The National Service Trust is the office within the Corporation that administers the education award

program. This involves tracking the service for all AmeriCorps members, ensuring that certain requirements of the Corporation's enabling legislation are met, and processing school and loan payments that the members authorize.

Current Action

After an AmeriCorps member completes a period of national service, the individual receives an education award that can be used to pay against qualified student loans or pay for current post secondary educational expenses. The Voucher and Payment Request Form is the document that a member uses to access his or her account in the National Service Trust.

The form serves three purposes: (1) The AmeriCorps member uses it to request and authorize a specific payment to be made from his or her account, (2) the school or loan company uses it to indicate the amount for which the individual is eligible, and (3) the school or loan company and member both certify that the payment meets various legislative requirements. When the Corporation receives a voucher, it is processed and the U.S. Treasury issues a payment to the loan holder or school on behalf of the AmeriCorps member.

The form was first designed and some variation of it has been in use since the summer of 1994. The proposed revisions are being made to clarify certain sections of the existing form. The voucher will include boxes for some of the responses, because the Corporation intends to scan the images and automatically retrieve some of the information. Currently, all of the information from the form is entered into the Corporation's database by hand. Automating part of this process should greatly decrease the processing time and decrease the number of payment errors.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: Voucher and Payment Request Form.

OMB Number: 3045–0014.

Agency Number: None.

Affected Public: Individuals who have completed a term of national service who wish to access their education awards.

Total Respondents: 55,000 responses annually (estimated annual average over the next three years).

Frequency: Experience has shown that some members may not ever use the education award and others use it several times a year.

Average Time Per Response: Total of 5 minutes (one half minute for the AmeriCorps member's section and 4½ minutes for the school or lender).

Estimated Total Burden Hours: 4,583 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: January 2, 2001.

Levon L. Buller,

Acting Director, National Service Trust.

[FR Doc. 01–371 Filed 1–4–01; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Form, and OMB Number: Personnel Security Clearance Change Notification; DISCO Form 562; OMB Number 0704–[To Be Determined].

Type of Request: New Collection.

Number of Respondents: 11,290.

Responses per Respondent: 20.

Annual Responses: 225,800.

Average Burden Per Response: 12 minutes.

Annual Burden Hours: 45,160.

Needs and Uses: The DISCO Form 562 is used by contractors participating in the National Industrial Security Program to report various changes in employee personnel clearance status or identification information. The execution of the form is a factor in making a determination as to whether a contractor employee is eligible to have a security clearance.

Affected Public: Business or other for-profit; not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Mr. Edward C. Springer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Cushing.

Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: December 27, 2000.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–283 Filed 1–4–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Form Number, and OMB Number: Description of Vessels, Description of Operations; ENG Form 3931, 3932; OMB Number 0710–0009.

Type of Request: Revision.

Number of Respondents: 2,500.

Responses Per Respondent: 1.

Annual Responses: 2,500.

Average Burden Per Response: 48 minutes.

Annual Burden Hours: 2,000.

Needs and Uses: The data collected provide information on vessel operators and their American Flag vessels operating or available for operation on the inland waterways of the United States in the transportation of freight and passengers. The information provides accurate U.S. Flag fleet statistics for use by the Army Corps of Engineers and other agencies, such as the U.S. Coast Guard and Federal and State agencies involved in transportation.

Affected Public: Business or Other For-Profit.

Frequency: Annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Mr. Jim Laity.

Written comments and recommendations on the proposed information collection should be sent to Mr. Laity at the Office of Management and Budget, Desk Officer for the U.S. Army Corps of Engineers, Room 10202, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Robert Cushing.

Written requests for copies of the information collection proposal should

be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: December 28, 2000.

Linda Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–284 Filed 1–4–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF EDUCATION

Submission of OMB Review; Comment Request

AGENCY: Department of Education.

ACTION: Correction Notice.

SUMMARY: On December 29, 2000, a 60-day notice inviting comment from the public was inadvertently published for the European Community/United States of America Cooperation Program in Higher Education and Vocational Education and Training in the **Federal Register** (65 FR 82985) dated December 29, 2000. This information collection is being submitted under the Streamlined Clearance Process for Discretionary Grant Information Collection (1890–0001). Therefore, this notice amends the public comment period for this program to 30 days. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, hereby issues a correction notice on the submission for OMB review as required by the Paperwork Reduction Act of 1995. Since an incorrect public notice was published on December 29, the Department of Education is correcting the end date to the 30 days as required for discretionary grants instead of 60 days.

DATES: Interested persons are invited to submit comments on or before January 26, 2001.

ADDRESSES: Written comment should be addressed to the Office of Information and Regulatory Affairs, Attention: Lauren Wittenberg, Acting Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW, Room 10235, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection request should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 5624, Regional Office Building 3, Washington, DC 20202–4651 or should be electronically mailed to the internet address *vivian reese@ed.gov* or should be faxed to 202–708–9346.

FOR FURTHER INFORMATION CONTACT: Joseph Schubart (202) 708–9266.

Dated: January 2, 2001.

John Tressler,

Leader, Regulatory Information Management, Office of the Chief Information Officer.

[FR Doc. 01–380 Filed 1–4–01; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Secretary of Energy Advisory Board

AGENCY: Department of Energy.

ACTION: Notice of open teleconference meeting.

SUMMARY: This notice announces a open teleconference meeting of the Secretary of Energy Advisory Board. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770), requires that agencies publish these notices in the **Federal Register** to allow for public participation. The purpose of the teleconference is to discuss the final findings and recommendations of the Secretary of Energy Advisory Board's Task Force on DOE Nonproliferation Programs in Russia, a subcommittee of the Secretary of Energy Advisory Board. Note: Copies of the draft final report of the Task Force on DOE Nonproliferation Programs in Russia may be obtained beginning January 10, 2001 from the following internet address http://www.hr.doe.gov/seab/ or by contacting the Office of the Secretary of Energy Advisory Board at (202) 586–7092. Name: Secretary of Energy Advisory Board

DATES: Thursday, January 18, 2001, 10 AM–11:30 PM, Eastern Standard Time.

ADDRESSES: Participants may call the Office of the Secretary of Energy Advisory Board at (202) 586–7092 to reserve a teleconference line and receive a call-in number. Public participation is welcomed. However, the number of teleconference lines are limited and are available on a first come basis.

FOR FURTHER INFORMATION CONTACT: Mary Louise Wagner, Executive Director, Secretary of Energy Advisory Board (AB–1), U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586–7092 or (202) 586–6279 (fax).

SUPPLEMENTARY INFORMATION: The purpose of the Secretary of Energy Advisory Board (The Board) is to provide the Secretary of Energy with essential independent advice and recommendations on issues of national importance. The Board and its subcommittees provide timely, balanced, and authoritative advice to the Secretary of Energy on the Department's management reforms, research, development, and technology activities, energy and national security responsibilities, environmental cleanup activities, and economic issues relating to energy. The Task Force on DOE Nonproliferation Programs in Russia, a subcommittee of the Secretary of Energy Advisory Board, was formed to appraise and provide recommendations to the Board on the policy priorities established by the Department in its cooperative nonproliferation and nuclear safety programs with Russia; to identify crucial program areas that may not have been addressed in the past; and to assess the performance of DOE's programs in achieving national security and nonproliferation missions. The Task Force was also tasked to assess the performance of DOE's programs in achieving its national security and nonproliferation missions, and provide policy recommendations on how the Department can be most effective in supporting U.S. national security interests.

Tentative Agenda

Thursday, January 18, 2001

10:00 AM–10:10 AM Welcome & Opening Remarks—Mr. Andrew Athy, Chairman of the Secretary of Energy Advisory Board

10:10 PM–10:30 PM Overview of the Task Force on DOE Nonproliferation Programs in Russia's Final Findings and Recommendations

10:30 PM–11:00 PM Public Comment Period

11:00 PM–11:30 PM Board Review & Comment and Action—Mr. Andrew Athy, Chairman of the Secretary of Energy Advisory Board

11:30 PM Adjourn

This tentative agenda is subject to change.

Public Participation

In keeping with procedures, members of the public are welcome to observe the business of the Secretary of Energy Advisory Board and submit written comments or comment during the scheduled public comment period. The Chairman of the Board is empowered to conduct the meeting in a fashion that will, in the Chairman's judgment, facilitate the orderly conduct of business. During its open teleconference meeting, the Board welcomes public comment. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. The Board will make every effort to hear the views of all interested parties. Written comments should be submitted no later than January 16, 2001 to Mary Louise

Wagner, Executive Director, Secretary of Energy Advisory Board, AB–1, US Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585.

Minutes

A copy of the minutes and a transcript of the open teleconference meeting will be made available for public review and copying approximately 30 days following the meeting at the Freedom of Information Public Reading Room, 1E–190 Forrestal Building, 1000 Independence Avenue, SW, Washington, DC, between 9 A.M. and 4 P.M., Monday through Friday except Federal holidays. Further information on the Secretary of Energy Advisory Board and its subcommittees may be found at the Board's web site, located at http://www.hr.doe.gov/seab.

Issued at Washington, DC, on January 2, 2001.

Carol Anne Kennedy,

Acting Advisory Committee Management Officer.

[FR Doc. 01–421 Filed 1–4–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–58–000]

Dominion Transmission, Inc.; Notice of Application

December 29, 2000.

Take notice that on December 22, 2000, Dominion Transmission, Inc. (DTI), 445 West Main Street, Clarksburg, West Virginia 26301, tendered for filing in Docket No. CP01–58–000, an abbreviated application for a blanket certificate pursuant to section 7 of the Natural Gas Act, as amended, and the Commission's Rules and Regulations thereunder, authorizing the utilization of coiled tubing drilling technology on existing storage wells for the purpose of improving deliverability and reservoir performance in certain storage reservoirs where DTI has not achieved its certificated deliverability. DTI claims that the drilling procedure will take place within the existing footprint of the storage wells. The blanket authorization would apply to the Bridgeport Field in Harrison County, West Virginia; the South Bend Field in Armstrong County, Pennsylvania; the Fink-Kennedy-Lost Creek Field in Lewis County, Pennsylvania; the Oakford Fifth Sand in Westmoreland County, Pennsylvania and the Oakford Murrysville in Westmoreland County, Pennsylvania, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may be viewed on the web at *http://www.ferc.fed.us./online/rims.htm* (call (202) 208–2222 for assistance).

According to DTI, it will use coiled tubing drilling technology to sidetrack existing storage wells with short (300′ to 500′) horizontal laterals to improve the deliverability and reservoir performance in certain storage reservoirs where other more conventional enhancement strategies are not effective or do not apply. DTI states that many of the wells in the candidate fields for the new technology have been historically poor performers and are located in less than optimum locations in the reservoir. By drilling horizontal laterals from the existing wellbores, DTI would be able to take advantage of pre-existing gathering line infrastructure, access roads, and well locations; reducing costs as well as eliminating any new environmental disturbances. DTI estimates the cost of the technology to be $575,000 per well to implement. DTI states that the drilling time of 5 to 7 days would make very temporary presence of equipment/environmental intrusion. DTI claims that the use of this technology will not result in the expansion of the active or protective portions of the storage reservoir.

Questions regarding the details of this application should be directed to Sean Sleigh, Certificates Manager, Dominion Transmission, Inc.; 445 West Main Street, Clarksburg, WV 26301, call (304)–627–3462, or fax (304)–627–3305.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before January 19, 2001, file with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

Comments and protests may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the

Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–300 Filed 1–4–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–59–000]

Eastern Shore Natural Gas Company; Notice of Application

December 29, 2000.

Take notice that on December 22, 2000, Eastern Shore Natural Gas Company (Eastern Shore), Post Office Box 1769, Dover, Delaware 19903–1769, filed in Docket No. CP01–59–000 an application pursuant to Section 7(c) of the Natural Gas Act for authorization to construct and operate additional pipeline and compression facilities in Maryland and Pennsylvania to expand its system by providing added transportation capacity, all as more fully set forth in the application on file with the Commission and open to public inspection. This filing may be viewed on the web at *http://www.ferc.fed.us/online/htm* (call 202–208–2222 for assistance).

Eastern Shore proposes to construct and operate 6 miles of 16-inch pipeline looping on its existing system in Maryland and Pennsylvania, to install 3,330 horsepower of additional capacity at the existing Daleville Compressor Station on Eastern Shore's system in Chester County, Pennsylvania, and to install delivery point facilities in Chester County, Pennsylvania. It is stated that the proposed construction would enable Eastern Shore to provide 19,800 dt equivalent of additional daily firm service capacity on its system. Eastern Shore estimates the total cost of the proposed facilities at $12,478,745. It is requested that a certificate be issued allowing construction to be completed by November 1, 2001.

Eastern Shore asserts that the facilities would provide system-wide benefits without requiring a rate increase for existing customers. Therefore, Eastern Shore requests a determination that the cost of the project be given rolled-in rate treatment. Eastern Shore convened an open season for the additional capacity and secured 10-year firm contracts with PECO Energy Company, Connectiv Power Delivery, and Delaware Division of Chesapeake Utilities Corporation for the additional capacity.

Any questions regarding the application should be directed to Stephen C. Thompson, President, Eastern Shore Natural Gas Company, 417 Bank Lane, Dover, Delaware 19904 (302) 734–6710.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 19, 2001, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules. Comments and protests may be filed electronically in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's website at http://ferc.fed.us/efi/doorbell.htm.

A person obtaining intervenor status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by every one of the intervenors. An intervenor can file for rehearing of any Commission order and can petition for court review of any such order. However, an intervenor must submit copies of comments or any other filing it makes with the Commission to every other intervenor in the proceeding, as well as 14 copies with the Commission.

A person does not have to intervene, however, in order to have comments considered. A person, instead, may submit two copies of comments to the Secretary of the Commission. Commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all parties. However, commenters will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek rehearing or appeal the Commission's final order to a federal court.

The Commission will consider all comments and concerns equally, whether filed by commenters or those requesting intervenor status.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Eastern Shore to appear or be represented at the hearing.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–299 Filed 1–4–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP99–600–000]

National Fuel Gas Distribution Corporation; Notice of Technical Conference

December 28, 2000.

Take notice that a technical conference will be held on Wednesday, January 10, 2001, at 2:00 p.m., in Room 3m–1 at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. On December 21, 2000, Norse Pipeline, L.L.C. and Nornew Energy, Inc. filed in request to meet with the Staff and interested parties regarding their options to address the jurisdictional issues raised by the Commission's December 14, 2000 Order Addressing Petition for Declaratory Order and Directing Compliance Filing (93 FERC 61,276 (2000)).

All interested parties and Staff are permitted to attend. For additional information, please contact Robert Christin (202) 208–1022.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–298 Filed 1–4–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–57–000]

SunCor Development Company; Notice of Petition

December 29, 2000.

Take notice that on December 21, 2000, SunCor Development Company (SunCor), 3838 North Central, Suite 1500, Phoenix, Arizona 85012, filed in Docket No. CP01–57–000, a Petition for Exemption of Temporary Acts and Operations from Certificate Requirements, pursuant to Rule 207(a)(5) of the Commission's Rules of Practice and Procedure (18 CFR 387.207(a)(5)), and section 7(c)(1)(B) of the Natural Gas Act (NGA), seeking approval of an exemption from certificate requirements to perform temporary activities related to drill site preparation and the drilling of a stratigraphic test well, all as more fully set forth in this petition which is on file with the Commission and open to public inspection. SunCor has requested expedited consideration of this Petition. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Specifically, SunCor seeks authorization to engage in certain temporary activities for the sole purpose of drilling a 5,200 foot stratigraphic test well in the Luke salt deposit located in Section 2, Township 2 North, Range 1 West, Maricopa County, Arizona. SunCor states the proposed stratigraphic test well is critical in determining of the Luke salt deposit would be suitable for development of a natural gas salt storage facility. SunCor states that it intends to conduct the well test in compliance with any environmental requirements of the Arizona Oil & Gas Conservation Commission. SunCor also requests that the Commission grant pregranted abandonment authority under Section 7(b) of the NGA to the extent it is necessary or required.

Any questions regarding this petition should be directed to Steve Garvais, Vice President and General Counsel, SunCor Development Company, 3838 North Central, Suite 1500, Phoenix, Arizona 85012 at (603) 285–6800.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before January 9, 2001, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and musts mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts form this proposal, it is important either to file comments or to intervene as early in the process as possible.

Comments and protests may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final commission order approving or denying a certificate will be issued.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–301 Filed 1–4–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG01–72–000, et al.]

Geysers Statutory Trust, et al.; Electric Rate and Corporate Regulation Filings

December 28, 2000.

Take notice that the following filings have been made with the Commission:

1. Geysers Statutory Trust

[Docket No. EG01–72–000]

Take notice that on December 19, 2000, Geysers Statutory Trust (Geysers Trust), tendered for filing with the Federal Energy Regulatory Commission (Commission) an application for determination of exempt wholesale generator (EWG) status pursuant to Part 365 of the Commission's Regulations.

Geysers Trust is a Connecticut statutory trust. Geysers Trust received an initial and second determination of EWG status in Docket EG99–120–000 by letter order dated May 7, 1999, Geysers Statutory Trust, 87 FERC 62,159 (1999), and in Docket EG00–16–000 by letter order dated December 28, 1999, Geysers Statutory Trust, 89 FERC 62,250 (1999), with respect to holding legal title to and leasing sixteen (16) geothermal generating facilities located in Lake County and Sonoma County, California. The instant application reflects that Geysers Trust will be the owner/lessor of three (3) additional geothermal generating facilities, the Bear Canyon kW #1 generating facility, the Bear Canyon kW #2 generating facility, and the West Ford Flat generating facility, having a collective net generating capacity of approximately forty-seven (47) megawatts, located in Lake County, California.

Geysers Trust further states that copies of the application were served upon the Securities and Exchange Commission and the California Public Utilities Commission.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. Geysers Power Company, LLC

[Docket No. EG01–73–000]

Take notice that on December 19, 2000, Geysers Power Company, LLC (Geysers Power), tendered for filing with the Federal Energy Regulatory Commission (Commission), an application for determination of exempt wholesale generator (EWG), status pursuant to Part 365 of the Commission's Regulations. Geysers Power is a Delaware limited liability company and an indirect wholly owned subsidiary of Calpine Corporation (Calpine). Geysers Power received determinations of EWG status in Docket No. EG99–109–000, by letter order dated April 28, 1999, Geysers Power Company, LLC, 87 FERC 62,115 (1999), and in Docket No. EG00–18–000 by letter order dated December 28, 2000, Geysers Power Company, LLC 89 FERC 62,251 (1999), with respect to its current lease and operation of sixteen (16) geothermal generating facilities located in Lake County and Sonoma County, California.

The instant application reflects that Geysers Power will operate, generate, and sell power exclusively for resale from three (3) additional geothermal power generation facilities, the Bear Canyon kW #1 generating facility, the Bear Canyon kW #2 generating facility, and the West Ford Flat generating facility, having a combined net generating capacity of approximately forty-seven (47) MW, located in Lake County, California.

Geysers Power further states that copies of the application were served upon the Securities and Exchange Commission and the California Public Utilities Commission.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

3. Attala Generating Company, LLC

[Docket No. EG01–74–000]

Take notice that on December 20, 2000, Attala Generating Company, LLC (Attala), a Delaware corporation with its principal place of business at 7500 Old Georgetown Road, Bethesda, Maryland 20814, tendered for filing with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

Attala proposes to own or lease and operate a natural gas-fired, combined cycle power plant of approximately 500 MW capacity in Attala County, Mississippi. The proposed power plant is expected to commence commercial operation in 2001. All output from the plant will be sold by Attala exclusively at wholesale.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

4. Badger Windpower, LLC

[Docket No. EG01–75–000]

Take notice that on December 20, 2000, Badger Windpower, LLC (the Applicant), with its principal office at 700 Universe Boulevard, Juno Beach, Florida 33408, tendered for filing with the Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

Applicant states that it is a Delaware limited liability company engaged directly and exclusively in the business of developing and operating an approximately 30 MW wind-powered generating facility located in the Township of Eden, Wisconsin. Electric energy produced by the facility will be sold at wholesale or at retail exclusively to foreign consumers.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy.

5. Elwood Energy III, LLC

[Docket No. EG01–78–000]

Take notice that on December 20, 2000, Elwood Energy III, LLC (Elwood), tendered for filing with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

Elwood is owned by Dominion Elwood III, Inc., a Delaware corporation, and Peoples Elwood III, LLC, a Delaware limited liability company. Dominion Elwood III, Inc., is a wholly-owned subsidiary of Dominion Generation, Inc., which in turn is a wholly-owned subsidiary of Dominion Resources, Inc. Peoples Elwood III, LLC is a wholly-owned subsidiary of PERC Power, Inc., which in turn is a wholly-owned subsidiary of Peoples Energy Resources, Corp.

Elwood will own and operate a generating facility with a nominal capacity of 300 MW located near Elwood Illinois, consisting of three 150 MW GE turbine generator sets, an approximately 0.3 mile long 345 kV transmission line, three 18/345 kV step up transformers, three 18kV/4160v auxiliary transformers, and associated circuit breakers. The facility will be interconnected with the transmission system of Commonwealth Edison Company.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

6. FPL Energy Vansycle, LLC

[Docket No. EG01–76–000]

Take notice that on December 20, 2000, FPL Energy Vansycle, LLC (the Applicant), with its principle office at 700 Universe Boulevard, Juno Beach, Florida 33408, tendered for filing with the Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

Applicant states that it is a Delaware limited liability company engaged directly and exclusively in the business of developing and operating an approximately 300 MW wind-powered generating facility located in Walla Walla County, Washington and Umatilla

County, Oregon. Electric energy produced by the facility will be sold at wholesale or at retail exclusively to foreign consumers.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

7. Elwood Energy II, LLC

[Docket No. EG01–77–000]

Take notice that on December 20, 2000, Elwood Energy II, LLC (Elwood), tendered for filing with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

Elwood is owned by Dominion Elwood II, Inc., a Delaware corporation, Peoples Elwood II, LLC, a Delaware limited liability company and SkyGen Energy LLC, also a Delaware limited liability company. Dominion Elwood II, Inc., is a wholly-owned subsidiary of Dominion Generation, Inc., which in turn is a wholly-owned subsidiary of Dominion Resources, Inc. Peoples Elwood II, LLC is a wholly-owned subsidiary of PERC Power, Inc., which in turn is a wholly-owned subsidiary of Peoples Energy Resources, Corp. SkyGen Energy LLC is owned by Calpine Corporation, a Delaware corporation located in San Jose, California.

Elwood will own and operate a generating facility with a nominal capacity of 300 MW located near Elwood Illinois, consisting of two 150 MW GE turbine generator sets, an approximately 0.3 mile long 345 kV transmission line, two 18/345 kV step up transformers, two 18kV/4160v auxiliary transformers, and associated circuit breakers. The facility will be interconnected with the transmission system of Commonwealth Edison Company.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

8. Steam Heat LLC

[Docket No. EG01–71–000]

Take notice that on December 19, 2000, Steam Heat LLC (Steam Heat), tendered for filing with the Federal Energy Regulatory Commission (Commission) an application for determination of exempt wholesale generator (EWG) status pursuant to Part 365 of the Commission's Regulations.

Steam Heat is a Delaware limited liability company. Steam Heat received an initial and second determination of EWG status in Docket EG99–121–000 by letter order dated May 7, 1999, Steam Heat LLC, 87 FERC 62,156 (1999), and in Docket EG00–17–000 by letter order dated December 14, 1999, Steam Heat LLC, 89 FERC 62,203 (1999), with respect to its beneficial ownership of sixteen (16) geothermal power generation facilities located in Lake County and Sonoma County, California. The instant application reflects that Steam Heat will be acquiring direct or indirect beneficial ownership interests in (a) three (3) additional geothermal generating facilities, the Bear Canyon kW #1 generating facility, the Bear Canyon kW #2 generating facility, and the West Ford Flat generating facility, having a collective net generating capacity of approximately forty-seven (47) megawatts, located in Lake County, California; (b) an undivided interest in the ''Morgantown Units,'' consisting of Baseload Units 1 and 2, a 1164 MW (net) coal/oil-fired electric generating facility located near Newburg, Maryland, interconnecting transmission facilities necessary to effect wholesale sales of energy from the facility and associated books and records; and (c) an undivided interest in the ''Dickerson Units,'' consisting of Baseload Units 1, 2 and 3, a 546 (net) coal/oil-fired electric generating facility located in Upper Montgomery, Maryland, interconnecting transmission facilities necessary to effect wholesale sales of energy from the facility and associated books and records.

Steam Heat further states that copies of the application were served upon the Securities and Exchange Commission, the California Public Utilities Commission, the Maryland Public Service Commission and the District of Columbia Public Service Commission.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

9. Ocean State Power and Ocean State Power II

[Docket Nos. ER00–1534–002, ER00–1535–002]

Take notice that on December 20, 2000, Ocean State Power and Ocean State Power II (Ocean State), tendered for filing its refund compliance report in the above-referenced dockets.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER01–612–000]

Take notice that on December 20, 2000, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC tendered for filing a request to withdraw its Market Rate Tariff Service Agreement No. 103 filed with the Commission in the above-referenced docket.

Copies of the filing have been provided to the Customer, to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, the West Virginia Public Service Commission, and all parties of record.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. Illinois Power Company

[Docket No. ER01–712–000]

Take notice that on December 20, 2000, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 65251–2200, tendered for filing an Interconnection Agreement entered into with Dynegy Midwest Generation, Inc. (DMG), and subject to Illinois Power's Open Access Transmission Tariff.

Illinois Power requests an effective date of December 1, 2000, for the Interconnection Agreement and seeks a waiver of the Commission's notice requirement. Illinois Power has served a copy of the filing on DMG.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. American Transmission Company, LLC

[Docket No. ER01–725–000]

Take notice that on December 20, 2000, American Transmission Company LLC (ATCLLC), tendered for filing a Network Operating Agreement and Network Integration Transmission Service Agreement between ATCLLC and Wisconsin Electric Power Company (WEPCO).

ATCLLC requests an effective date of January 1, 2001.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

13. American Transmission Company, LLC

[Docket No. ER01–726–000]

Take notice that on December 20, 2000, American Transmission Company

LLC (ATCLLC), tendered for filing a Network Operating Agreement and Network Integration Transmission Service Agreement between ATCLLC and the City of Stoughton.

ATCLLC requests an effective date of January 1, 2001.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

14. New York State Electric & Gas Corporation

[Docket No. ER01–734–000]

Take notice that on December 20, 2000, New York State Electric & Gas Corporation (NYSEG), tendered for filing pursuant to section 35 of the Federal Energy Regulatory Commission's Regulations, 18 CFR 35, a service agreement (the Service Agreement) under which NYSEG may provide capacity and/or energy to Conectiv Energy Supply, Inc. (Conectiv) in accordance with NYSEG's FERC Electric Tariff, Original Volume No. 3.

NYSEG has requested waiver of the notice requirements so that the Service Agreement becomes effective as of December 21, 2000.

NYSEG has served copies of the filing upon the New York State Public Service Commission and Conectiv.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

15. Puget Sound Energy, Inc.

[Docket No. ER01–735–000]

Take notice that on December 20, 2000, Puget Sound Energy, Inc. (PSE), tendered for filing a Service Agreement under PSE's Electric Tariff, First Revised Volume No. 8 (Market Rate Tariff) with the California Independent System Operator (the Cal ISO).

A copy of the filling was served upon the Cal ISO.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

16. Automated Power Exchange, Inc.

[Docket No. ER01–736–000]

Take notice that on December 20, 2000, Automated Power Exchange, Inc., tendered for filing a rate schedule under which APX will offer power exchange services in the APX New York Market.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

17. Wisconsin Power & Light Company

[Docket No. ER01–737–000]

Take notice that on December 20, 2000, Wisconsin Power & Light Company (WPL), tendered for filing a Service Agreement with the City of Kiel.

WPL indicates that copies of the filing have been provided to the Kiel and to the Public Service Commission of Wisconsin.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

18. Conoco, Inc.

[Docket No. ER01–738–000]

Take notice that on December 19, 2000, Conoco, Inc., tendered for filing pursuant to §§ 35.16 and 35.151 of the Federal Energy Regulatory Commission's (Commission) Regulations, 18 CFR 35.16 and 35.151 Conoco Power Marketing, Inc., a Delaware Corporation and an wholly owned subsidiary of Conoco Petroleum Operations, Inc., which is a wholly owned subsidiary of Conoco Inc., 600 North Dairy Ashford Road, Houston, Texas, hereby gives notice of transfer of Certificate of Public Convenience and Necessity to parent corporation Conoco, Inc. This transfer is the result of an internal reorganization of Conoco Inc.'s power trading activities.

Conoco Inc., on December 18, 2000, hereby adopts, ratifies, and makes its own, in every respect all applicable rate schedules, and supplements thereto, listed below, hereto filed with the Commission by Conoco Power Marketing, Inc., effective as of the date of a Commission order granting approval of FERC Electric Schedule No. 1.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

19. American Transmission Company, LLC

[Docket No. ER01–727–000]

Take notice that on December 20, 2000, American Transmission Company LLC (ATCLLC), tendered for filing four short-term firm and non-firm service agreements for point-to-point transmission service with Northern Indiana Public Service Company LLC and Split Rock Energy LLC.

ATCLLC requests an effective date of January 1, 2001.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

20. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER01–730–000]

Take notice that on December 20, 2000, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC (Allegheny Energy Supply), tendered for filing Service Agreement No. 104 to add one (1) new Customer to the Market Rate Tariff under which Allegheny Energy Supply offers generation services. Allegheny Energy Supply proposes to make service available as of December 19, 2000 to CNG Power Services Corporation.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, the West Virginia Public Service Commission, and all parties of record.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

21. American Electric Power Service Corporation

[Docket No. ER01–720–000]

Take notice that on December 20, 2000, the American Electric Power Service Corporation (AEPSC) as agent for Indiana Michigan Power Company, tendered for filing an executed Interconnection and Operation Agreement between Indiana Michigan Power Company and Duke Energy DeSoto, LLC. The agreement is pursuant to the AEP Companies' Open Access Transmission Service Tariff (OATT) that has been designated as the Operating Companies of the American Electric Power System FERC Electric Tariff Revised Volume No. 6, effective June 15, 2000.

AEP requests an effective date of March 1, 2001.

A copy of the filing was served upon the Indiana Utilities Regulatory Commission and the Michigan Public Service Commission.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

22. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER01–728–000]

Take notice that on December 20, 2000, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC (Allegheny Energy Supply), tendered for filing Service Agreement No. 106 to add one (1) new Customer to the Market Rate Tariff under which Allegheny Energy Supply offers generation services.

Allegheny Energy Supply requests a waiver of notice requirements for an effective date of November 28, 2000 for Merrill Lynch Capital Services, Inc.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, the West Virginia Public Service Commission, and all parties of record.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

23. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER01–729–000]

Take notice that on December 20, 2000, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC (Allegheny Energy Supply), tendered for filing Service Agreement No. 105 to add one (1) new Customer to the Market Rate Tariff under which Allegheny Energy Supply offers generation services.

Allegheny Energy Supply requests a waiver of notice requirements for an effective date of November 27, 2000 for Alliant Energy Corporate Services, Inc.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, the West Virginia Public Service Commission, and all parties of record.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

24. St Joseph Light & Power Company

[Docket No. ER01–732–000]

Take notice that on December 20, 2000, St. Joseph Light & Power Company (SJLP), tendered for filing five executed agreements for transmission service under its Open Access Transmission Tariff. The five agreements consist of two agreements (one agreement for firm point-to-point service, and a second agreement for non-firm point-to-point service) for each of two transmission customers—Cargill-Alliant, LLC and Municipal Energy Agency of Nebraska—and one agreement (for non-firm point-to-point service) for Engage Energy US, L.P.

SJLP states that copies of this filing have been served on each of these three entities.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at this end of the notice.

25. Virginia Electric and Power Company

[Docket No. ER01–733–000]

Take notice that on December 20, 2000, Virginia Electric and Power Company (Dominion Virginia Power or the Company), tendered for filing a Service Agreement for Retail Network Integration Transmission Service, Network Operating Agreement, and Retail Network Transmission Service (Service Agreement) by Virginia Electric and Power Company to PEPCO Energy Services, Inc., designated as Service Agreement No. 311 under the Company's Retail Access Pilot Program, pursuant to Attachment L of the Company's Open Access Transmission Tariff, FERC Electric Tariff, Second Revised Volume No. 5, to Eligible Purchasers effective June 7, 2000.

Dominion Virginia Power requests an effective date of December 20, 2000, the date of filing of the Service Agreements.

Copies of the filing were served upon PEPCO Energy Services, Inc., the Virginia State Corporation Commission, and the North Carolina Utilities Commission.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

26. American Electric Power Service Corporation

[Docket No. ER01–741–000]

Take notice that on December 21, 2000, the American Electric Power Service Corporation (AEPSC), tendered for filing executed Interconnection and Operation Agreement between Kentucky Power Company and Riverside Generating Company, LLC, as construction agent for the Lawrence County Riverside Trust 2000. The agreement is pursuant to the AEP Companies' Open Access Transmission Service Tariff (OATT) that has been designated as the Operating Companies of the American Electric Power System FERC Electric Tariff Revised Volume No. 6, effective June 15, 2000.

AEP requests an effective date of March 2, 2000.

A copy of the filing was served upon the Kentucky Public Service Commission.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

27. UtiliCorp United Inc.

[Docket No. ER01–742–000]

Take notice that on December 21, 2000, UtiliCorp United Inc. (UtiliCorp), tendered for filing a market-based sales tariff for St. Joseph Light & Power, an operating division.

UtiliCorp requests that the Commission accept the tariff for filing to become effective on January 1, 2001.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

28. Orion Power MidWest, L.P.

[Docket No. ER01–759–000]

Take notice that on December 22, 2000, Orion Power MidWest, L.P. (Orion Power MidWest), tendered for filing with the Federal Energy Regulatory Commission an Amended and Restated POLR II Agreement with Duquesne Light Company (Duquesne), designated as FERC Rate Schedule No. 8 for the sale of 100% of the wholesale power that Duquesne needs to meet its obligation as the provider of last resort during the post-transition period, *i.e.,* the period between the completion of Duquesne's competitive transition charge recovery through December 21, 2004. In exchange, Duquesne will make payments to Orion Power MidWest based on the generation portion Duquesne's unbundled retail rates.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A.Watson, Jr.,

Acting Secretary.

[FR Doc. 01–297 Filed 1–4–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC01–45–000, et al.]

P&L Coal Holdings Corporation, et al.; Electric Rate and Corporate Regulation Filings December 27, 2000.

Take notice that the following filings have been made with the Commission:

1. P&L Coal Holdings Corporation

[Docket No. EC01–45–000]

Take notice that on December 20, 2000, P&L Coal Holdings Corporation filed an application pursuant to section 203 of the Federal Power Act for an order authorizing the proposed sale of equity interests in CL Power Sales One, L.L.C., CL Power Sales Two, L.L.C., CL Power Sales Six, L.L.C., CL Power Sales Seven, L.L.C., CL Power Sales Eight, L.L.C., CL Power Sales Nine, L.L.C., and CL Power Sales Ten, L.L.C. to GATX Capital Corporation or a subsidiary thereof. The proposed transaction involves the sale of equity interests in power marketers subject to the Commission's jurisdiction.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

2. Virginia Electric and Power Company

[Docket No. EC01–46–0000]

Take notice that on December 15, 2000, Virginia Electric and Power Company (Applicant) tendered for filing an application pursuant to section 203 of the Federal Power Act for the purchase of certain jurisdictional transmission facilities appurtenant to the purchase of qualifying facilities from Westpower-Franklin, L.P., LG&E Southampton, L.P., LG&E Power 11 Incorporated, Westpower—Altavista, L.P., LG&E Altavista, L.P., LG&E Power 12 Incorporated, Westpower—Hopewell, L.P., LG&E Hopewell, L.P., and LG&E Power 13 Incorporated. Applicant states that copies of the application have been served upon the utility commissions of the states of Virginia and North Carolina and Applicant's wholesale requirements customers.

Comment date: January 8, 2001, in accordance with Standard Paragraph E at the end of this notice.

3. The Montana Power Company NorthWestern Corporation

[Docket No. EC01–47–000]

Take notice that on December 20, 2000, The Montana Power Company (Montana Power) and NorthWestern Corporation (NorthWestern), tendered for filing with the Federal Energy Regulatory Commission an application pursuant to section 203 of the Federal Power Act for authorization of a disposition of jurisdictional facilities whereby NorthWestern will purchase Montana Power's utility business in exchange for cash and the assumption of debt. The proposed transaction involves the purchase of all of Montana Power's regulated electric and natural gas utility facilities in Montana, as well as certain subsidiaries of Montana Power.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

4. Hafslund Energy Trading, LLC

[Docket No. EC01–48–000]

Take notice that on December 21, 2000, Hafslund Energy Trading, LLC (Hafslund), tendered for filing an application pursuant to section 203 of the Federal Power Act for authorization for the disposition of certain of its wholesale power agreements and associated books and records to Merrill Lynch Capital Services, Inc.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

5. Duke Energy Hinds, LLC

[Docket No. EG01–65–000]

Take notice that on December 15, 2000, Duke Energy Hinds, LLC (Duke Hinds), tendered for filing an application with the Federal Energy Regulatory Commission (the Commission) for determination of exempt wholesale generator status pursuant to Section 32 of the Public Utility Holding Company Act of 1935, as amended and Part 365 of the Commission's Regulations.

Duke Hinds is a Delaware limited liability company that will be engaged directly and exclusively in the business of owing and operating all or part of one or more eligible facilities to be located in Jackson, Mississippi. The eligible facilities will consist of an approximately 500 MW natural gas-fired, combined cycle electric generation plant and related interconnection facilities. The output of the eligible facilities will be sold at wholesale.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

6. PEI Power II, LLC

[Docket No. EG01–79–000]

Take notice that on December 20, 2000, PEI Power II, LLC, 2 Court Street, Binghamton, New York 13901, tendered for filing with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

The applicant is a limited liability company that will be engaged directly and exclusively in the business of owning or operating, or both owning and operating, an eligible facility (the Facility) in Archbald, Pennsylvania. The Facility will consist of a 45 MW generating unit fueled by natural gas and interconnection facilities necessary to interconnect the Facility to the local transmission grid.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

7. Dynegy Power Marketing, Inc., El Segundo Power, LLC., Long Beach Generation LLC, Cabrillo Power I LLC, Cabrillo Power II LLC v. California Independent System Operator Corporation

[Docket No. EL01–23–000]

Take notice that the above listed entities (Complainant) on December 22, 2000, tendered for filing a complaint under the Commission's fast-track procedures against the California Independent System Operator Corporation (ISO). Complainant has requested that the Commission direct the ISO to cease and desist making Out-of-Market (OOM) dispatch orders on its units in non-emergency situations, require the ISO to negotiate compensatory rates for OOM dispatch orders, file for a third payment option that generators subject to a Participating Generator Agreement could elect as compensation for OOM dispatch orders, and other related relief.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice. Answers to the compliant shall also be due on or before January 11, 2001.

8. The Montana Power Company

[Docket No. ER97–449–001]

Take notice that on December 20, 2000, The Montana Power Company (Montana Power) tendered for filing a notice of change of status and a revised statement of policy and standards of conduct to reflect a planned transaction pursuant to which NorthWestern

Corporation will purchase the utility business of Montana Power.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. American Electric Power Service Corporation

[Docket No. ER01–721–000]

Take notice that on December 20, 2000, the American Electric Power Service Corporation (AEPSC), tendered for filing executed Interconnection and Operation Agreement between Indiana Michigan Power Company and PSEG Lawrenceburg Energy Company, LLC. The agreement is pursuant to the AEP Companies' Open Access Transmission Service Tariff (OATT) that has been designated as the Operating Companies of the American Electric Power System FERC Electric Tariff Revised Volume No. 6, effective June 15, 2000.

AEP requests an effective date of February 1, 2001.

A copy of the filing was served upon the Indiana Utility Regulatory Commission and the Michigan Public Service Commission.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. UtiliCorp United, Inc.

[Docket No. ER01–723–000]

Take notice that on December 21, 2000, UtiliCorp United Inc. (UtiliCorp), tendered for filing amendments to the open access transmission tariffs for its Missouri Public Service, WestPlains Energy-Kansas, WestPlains Energy-Colorado and St. Joseph Power & Light operating divisions. The amendments ensure that transmission customers taking service over more than one UtiliCorp division do not pay UtiliCorp multiple transmission charges for such service.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. Illinois Power Company

[Docket No. ER01–722–000]

Take notice that on December 20, 2000, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 65251–2200, filed the following service agreements entered into pursuant to its Open Access Transmission Tariff: Service Agreement for Non-Firm Point-To-Point Transmission Service with Madison Gas and Electric Company (MGE), dated November 21, 2000; Service Agreement for Firm Short-Term Point-To-Point Transmission Service with MGE, dated November 21, 2000; Service Agreement for Non-Firm Point-To-Point Transmission Service with Southwestern Public Service Company (SWPS), dated November 22, 2000; Service Agreement for Firm Short-Term Point-To-Point Transmission Service with SWPS, dated November 22, 2000; and four (4) Service Agreements for Firm Long-Term Point-To-Point Transmission Service with Dynegy Power Marketing, Inc. (DPM), dated October 17, 2000.

Illinois Power requests effective dates of November 21, 2000 for the Agreements with MG&E; November 22, 2000 for the Agreements with SWPS; and January 1, 2001 for the Agreements with DPM. Accordingly, Illinois Power seeks a waiver of the Commission's notice requirement.

Illinois Power has served a copy of the filing on MGE, SWPS and DPM.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Central Illinois Light Company; Cinergy Corp.; Hoosier Energy R.E.C., Inc.; Southern Illinois Power Cooperative; Southern Indiana Gas & Electric Company; and Wabash Valley Power Association, Inc.

[Docket No. ER01–731–000]

Take notice that on December 20, 2000, Central Illinois Light Company, Cinergy Corp., Hoosier Energy R.E.C., Inc., Southern Illinois Power Cooperative, Southern Indiana Gas & Electric Company and Wabash Valley Power Association, Inc. (Designated Transmission Owners) tendered for filing: (1) Their notice of withdrawal, and request for authorization from the Federal Energy Regulatory Commission (Commission) for their withdrawal, from the Midwest Independent Transmission System Operator, Inc. (Midwest ISO), effective under the Federal Power Act as of the date upon which the Commission first allows the withdrawal from the Midwest ISO by Illinois Power Company, Commonwealth Edison Company and/or Ameren to take effect; and (2) their request that the Commission authorize a Designated Transmission Owner having Commission jurisdictional rates and charges to recover, through its Commission jurisdictional transmission service rates and charges, the costs incurred by the Designated Transmission Owner as a result of its withdrawal from the Midwest ISO.

Copies of the filing were served upon the Midwest ISO, Illinois Power Company, Commonwealth Edison Company, Ameren, the Indiana Utility Regulatory Commission, the Illinois Commerce Commission, the Public Utilities Commission of Ohio, the Kentucky Public Service Commission, the Public Service Commission of Wisconsin, the Michigan Public Service Commission and the Missouri Public Service Commission.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/ online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–296 Filed 1–4–01; 8:45 am]

BILLING CODE 6717–01–U

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

December 29, 2000.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Amendment of License.

b. *Project No.:* 2017–014.

c. *Date Filed:* January 12, 2000.

d. *Applicant:* Southern California Edison Company (SCE).

e. *Name of Project:* Big Creek No. 4 Hydroelectric Project.

f. *Location:* On San Joaquin in Fresno County, Fresno, California. The project is located within the Sierra National Forest.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant's Contact:* Stephen E. Pickett, 2244 Walnut Grove Ave., Rosemead, CA 91770, (626) 302–4459.

i. *FERC Contact:* Any questions on this notice should be addressed to Doan Pham at (202) 219–2851 or e-mail address *doan.pham@ferc.fed.us.*

j. Deadline for filing comments, motions to intervene, or protests: February 5, 2001.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

Please include the Project Number (2017–014) on any comments, protests, or motions filed.

k. *Description of Amendment:* SCE filed an application to reflect changes in transmission line and related facilities. SCE proposes to remove (1) the 5.8-miles transmission line from Big Creek #4 switchyard to Big Creek #3 switchyard, and (2) the 132.6-mile transmission line from Big Creek #4 switchyard to Springville to Magunden Substation from the project boundary, because they are part of SCE's interconnected system. SCE also proposes to revise the boundary line around the reservoir, and to remove an access road and communication and telephone lines from the project boundary. The changes will reduce the project area on lands that are managed by the U.S. Forest Service. In this proceeding we will only address the proposal to remove the subject transmission line and related facilities. The project boundary change is part of the re-licensing proceeding.

1. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC, 20426, or by calling (202) 208–1371. This filing may be viewed on http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the addresses in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.fer.fed.us/efi/doorbell.htm.*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–302 Filed 1–4–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Regulations Governing Off-the-Record Communications; Public Notice

December 29, 2000.

This constitutes notice, in accordance with 18 CFR 385.220(h), of the receipt of exempt and prohibited off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive an exempt or a prohibited off-the-record communication relevant to the merits of a contested on-the-record proceeding, to deliver a copy of the communication, if written, or a summary of the substance of any oral communication, to the Secretary.

Prohibited communications will be included in a public, non-decisional file associated with, but not part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such requests only when it determines that fairness so requires.

Exempt off-the-record communications will be included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of exempt and prohibited off-the-record communications received in the Office of the Secretary within the preceding 14 days. The documents may be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Exempt

1. P–2661, 12–26–00, Gary Taylor,
2. CP00–6–000, 12–21–00, Tim Blewett,
3. EL00–95–000, 12–20–00, G. Richard Judd,
4. CP00–6–000, 12–20–00, Sally B. Mann,
5. CP00–6–000, 12–20–00, Jon Schmidt,
6. CP00–6–000, 12–20–00, Susan Olson,
7. CP01–1–000, 12–20–00, Timothy Carey,
8. P–2342–011, 12–20–00, Frank Backus,
9. EL00–95–000, 12–19–00, Kathleen Vaughn,
10. CP98–150–000, 12–20–00, Matthew Brower.

Prohibited

None.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–303 Filed 1–4–01; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6930–1]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Information Collection Request for the State Source Water Assessment and Protection Programs 1997 Guidance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that the following continuing Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: The State Source Water Assessment and Protection Programs 1997 Guidance; EPA ICR #1816.02; OMB Control #2040–0197; expiration December 31, 2000. The ICR describes the nature of the information collection and its expected burden and cost; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before February 5, 2001.

ADDRESSES: Send comments, referencing EPA ICR No. 1816.02 and OMB Control Number 2040–0197, to the following addresses: Sandy Farmer, U.S. Environmental Protection Agency Collection Strategies Division (2822), 1200 Pennsylvania Ave, NW, Washington, DC 20460; and to Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: For a copy of the ICR contact Sandy Farmer EPA by phone at (202) 260–2740, by E-mail at farmer.sandy@epamail.epa.gov, or download off the Internet at *http://www.epa.gov/icr* and refer to EPA ICR No. 1816.02. For technical questions about the ICR contact Roy Simon, (202) 260–7777.

SUPPLEMENTARY INFORMATION:

Title: State Source Water Assessment and Protection Programs 1997 Guidance; OMB Control #2040–0197; EPA ICR #1816.02; expiring December 31, 2000. This renewal is a request for extension of a currently approved collection.

Abstract: Section 1453(a)(3) of the Safe Drinking Water Act Amendments of 1996 required States to submit a Source Water Assessment Program (SWAP) within 18 months after the guidance was issued, on or before August 6, 1997. These SWAP's describe how a State will delineate source water protection areas, conduct contamination source inventories and susceptibility determinations, makes the assessments available to the public, implement a Source Water Protection Program. A State must develop a SWAP program with public participation.

Once a State program is approved by EPA, the State has two years to complete the source water assessment for the public water systems within their borders. Section 1453(a)(4) of the SDWA Amendments of 1996 allows a State to request an extension of up to 18 months to complete the assessments. This final phase of this ICR will focus on the years 2000–2002 of the SWAP program, including completing the assessments, and State reporting of data on the required assessments to EPA.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and,

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The Federal Register document required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on June 16, 2000; No comments were received.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 50,169 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to implement the source water assessments; review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: States, Puerto Rico and District of Columbia.

Estimated Number of Respondents: 52.

Frequency of Response: Annually.

Estimated Total Annual Hour Burden: 2,608,787 hours.

Estimated Total Annualized Capital and Operating & Maintenance Cost Burden: $7,101,564.00.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the addresses listed above. Please refer to EPA ICR No. 1816.02 and OMB Control No. 2040–0197 in any correspondence.

Dated: December 29, 2000.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 01–363 Filed 1–4–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6929–7]

Acid Rain NO_X Emission Reduction Program—Permit Modification for Alternative Emission Limitation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of permit modification adopting Alternative Emission Limitation.

SUMMARY: Under Title IV of the Clean Air Act, EPA established the Acid Rain NO_X Emission Reduction Program to reduce the adverse effects of acidic deposition. EPA adopted nitrogen oxides (NO_X) emission limits and issued permits to affected sources. EPA is issuing Acid Rain permit modifications for two units at a source. Each permit modification adds a new NO_X emission limitation, *i.e.,* Alternative Emission Limitation for

NO_X emissions to the permit for the source. The Alternative Emission Limitations are less stringent than the standard limit for this type of unit but are the minimum rate that the units can achieve during long-term dispatch operation with low NO_X burners.

ADDRESSES: *Administrative Records.* The administrative record for the permit modification, except information protected as confidential, may be viewed during normal operating hours at the following location: EPA Region 3, 1650 Arch Street 14th floor, Philadelphia, PA.

FOR FURTHER INFORMATION CONTACT: Linda Miller, EPA Region 3, (215) 814–2068.

SUPPLEMENTARY INFORMATION: In today's action, EPA is issuing permit modifications that add to a permit Alternative Emission Limitations for NO_X emissions for two units in accordance with Parts 72 and 76 of the Acid Rain Program regulations. The units involved, Morgantown Units 1 and 2, are located in Charles County, Maryland and will be required to meet an annual average emissions limit for NO_X of 0.63 lb/mmBtu and 0.64 lb/mmBtu, respectively, instead of the otherwise applicable standard limit of 0.45 lb/mmBtu. The units' designated representative is James S. Potts.

Dated: December 27, 2000.

Larry F. Kertcher,

Acting Director, Clean Air Markets Division, Office of Atmospheric Programs, Office of Air and Radiation.

[FR Doc. 01–366 Filed 1–4–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6614–3]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or www.epa.gov/oeca/ofa.

Weekly receipt of Environmental Impact Statements Filed December 26, 2000 Through December 29, 2000 Pursuant to 40 CFR 1506.9.

EIS No. 000465, Final EIS, AFS, ID, Lakeface-Lamb Fuel Reduction Project, To Reduce the Risk of Lethal Fires within a Wildland/Urban Interface, Implementation, Idaho Panhandle National Forests, Priest Lake Ranger District, Bonner County, ID, Due: January 29, 2001, Contact: David Asleson (208) 443–2512.

This Notice of Availability should have appeared in the 12/29/2000 FR. The Official Wait Period began on 12/29/2000 and ends on 01/29/2001.

EIS No. 000466, Draft EIS, AFS, ID, MT, Lemhi Pass National Historic Landmark Management Plan, Implementation, Beaverhead-Deerlodge National Forest, Beaverhead County, MT and Salmon-Challis National Forest, Lemhi County, ID, Due: February 20, 2001, Contact: Katie R. Bump (406) 683–3900.

EIS No. 000467, Final Supplement, AFS, UT, Rhyolite Fuel Reduction Project to the South Spruce Ecosystem Rehabilitation Project, Implementation, Dixie National Forest, Cedar City Ranger District, Iron County, UT, Due: February 05, 2001, Contact: Phillip G. Eisenhauer (435) 865–3200.

EIS No. 000468, Draft Supplement, AFS, UT, Rendezvous Vegetation Management Project to the South Spruce Ecosystem Rehabilitation Project, Implementation, Dixie National Forest, Cedar City Ranger District, Iron and Kane Counties, UT, Due: February 20, 2001, Contact: Phillip G. Eisenhauer (435) 865–3200.

EIS No. 000469, Draft EIS, AFS, MI, Plantation Lakes Vegetation Management Project, Implementation, Ottawa National Forest, Kenton and Ontonagon Ranger Districts, Houghton County, MI, Due: February 20, 2001, Contact: Karen Stevens (906) 884–2411.

EIS No. 000470, Draft EIS, AFS, WI, Boundary Waters Canoe Area Wilderness Fuel Treatment, Implementation, Superior National Forest, Cook County, WI, Due: February 20, 2001, Contact: Joyce Thompson (218) 626–4317.

EIS No. 000471, Draft EIS, USN, FL, Renewal of Authorization to Use Pinecastle Range, Continue Use of the Range for a 20-Year Period, Special Use Permit Issuance, Ocala National Forest, Marion and Lake Counties, FL, Due: February 20, 2001, Contact: Darrell Molzan (843) 820–5796.

EIS No. 000472, Final EIS, SFW, WA, Tacoma Water Green River Water Supply Operations and Watershed Protection Habitat Conservation Plan, Implementation, Issuance of a Multiple Species Permit for Incidental Take, King County, WA, Due: February 5, 2001, Contact: Tim Romanski (360) 753–5823.

Dated: January 02, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 01–378 Filed 1–4–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6614–4]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 14, 2000 (65 FR 20157).

Final EISs

ERP No. F–AFS–J65293–MT

Taylor Fork Timber Sale and Road Restoration, Implementation, Buck Creek, Taylor Fork Creek and Eldridge Creek, Gallatin National Forest, Madison Ranger, Hebgen Lake Ranger District, Yellow Stone, Gallatin County, MT.

Summary: EPA expressed environmental concerns about the potential for delivery of sediment to Taylor Creek a 303(d) listed stream, but also indicated that project modifications should substantially mitigate effects. EPA recommended that aquatic effects on the Taylor Fork should be monitored to identify the actual impacts from the implementation activities. EPA believes additional information is needed to fully assess and mitigate all potential impacts of the management actions.

ERP No. F–SFW–K64017–CA

Trinity River Mainstem Fishery Restoration, To Restore and Maintain the Natural Production of Anadromous Fish, Trinity and Humboldt Counties, CA.

Summary: EPA urged approval, funding, and implementation of the Preferred Alternative as soon as possible and the amendment of BOR's existing SWRCB water permit to be consistent with the minimum instream flows, minimum reservoir storage, and TRD operational requirements of this alternative.

ERP No. FB–NPS–K61029–CA

Yosemite Valley Plan, Resource Preservation and Restoration, Visitor Enjoyment, Transportation and Employee Housing, Implementation, Yosemite National Park, Mariposa County, CA.

Summary: EPA reviewed the FSEIS and found that the document adequately addresses the issues raised in our comment letter. Therefore, EPA has no objection to the action as proposed.

Dated: January 2, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 01–379 Filed 1–4–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6930–3]

Availability of FY 99 Grant Performance Reports for States of Georgia and Mississippi, and the Commonwealth of Kentucky

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of grantee performance evaluation reports.

SUMMARY: EPA's grant regulations (40 CFR 35.150) require the Agency to evaluate the performance of agencies which receive grants. EPA's regulations for regional consistency (40 CFR 56.7) require that the Agency notify the public of the availability of the reports of such evaluations. EPA recently performed end-of-year evaluations of three state air pollution control programs (States of Georgia and Mississippi, and the Commonwealth of Kentucky). The three evaluations were conducted to assess the agencies' performance under the grants awarded by EPA under authority of section 105 of the Clean Air Act. EPA Region 4 has prepared reports for each agency identified above and these reports are now available for public inspection.

ADDRESSES: The reports may be examined at the EPA's Region 4 office, 61 Forsyth Street, SW, Atlanta, Georgia 30303, in the Air, Pesticides, and Toxics Management Division.

FOR FURTHER INFORMATION CONTACT: Gloria Knight, (404) 562–9064, at the above Region 4 address, for information concerning the State of Mississippi, and Marie Persinger (404) 562–9048 for the State of Georgia and the Commonwealth of Kentucky.

Dated: December 22, 2000.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 01–364 Filed 1–4–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–991; FRL–6761–9]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–991, must be received on or before February 5, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–991 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Kerry Leifer, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8811; e-mail address: leifer.kerry@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–991. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–991 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs

(OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 22, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Gustafson LLC,

PP 6F4682

EPA has received a pesticide petition PP6F4682 from Gustafson LLC, 1400 Preston Road, Suite 400, Plano, TX 75093 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of imidacloprid: 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine in or on the raw agricultural commodities: corn, field fodder at 0.20 parts per million (ppm); corn, field forage at 0.10 ppm; and corn, field grain at 0.05 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of imidacloprid in plants is adequately understood for the purposes of these tolerances. The residues of concern are combined residues of imidacloprid and its metabolites containing the 6-chloro-pyridinyl moiety, all calculated as imidacloprid.

2. *Analytical method*. The analytical method is a common moiety method for imidacloprid and its metabolites containing the 6-chloro-pyridinyl moiety using a permanganate oxidation, silyl derivatization, and capillary GC-MS selective ion monitoring. This method has successfully passed a petition method validation in EPA labs. There is a confirmatory method specifically for imidacloprid and several metabolites utilizing GC/MS and HPLC-UV which has been validated by the EPA as well. Imidacloprid and its metabolites are stable for at least 24 months in the commodities when frozen.

3. *Magnitude of residues*. Corn seed was treated with imidacloprid, formulated as Gaucho 480 FS at a rate of 8.0 oz.ai/cwt seed. Field trials were conducted at twenty locations, one in Region 1, one in Region 2, seventeen in Region 5, and one in Region 6. The corn seed was planted and the RACs were harvested at the appropriate growth stages. The highest average residue level found in field corn forage was 0.064 ppm. The highest average residue level found in the field corn grain was less than the Limit of Quantitation, which was 0.05 ppm. The highest average residue level found in the field corn fodder was 0.150 ppm. The proposed tolerance for field corn forage is 0.10 ppm. The proposed tolerance for the field corn fodder is 0.20 ppm. The

proposed tolerance for the field corn grain is 0.05 ppm.

Since there were no quantifiable residues in the field corn grain RAC samples analyzed in the processing study or in the RAC study, neither a Section 409 food/feed additive tolerance or a Section 701 maximum residue level is required for the processed commodities.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral LD_{50} values for imidacloprid technical ranged from 424 - 475 milligrams/kilograms (mg/kg) body weight (bwt) in the rat. The acute dermal LD_{50} was greater than 5,000 mg/kg in rats. The 4–hour inhalation LC_{50} was less than 69 mg/m^3 air (aerosol). Imidacloprid was not irritating to rabbit skin or eyes. Imidacloprid did not cause skin sensitization in guinea pigs.

2. *Genotoxicity*. Extensive mutagenicity studies conducted to investigate point and gene mutations, DNA damage and chromosomal aberration, both using *in vitro* and *in vivo* test systems show imidacloprid to be non–genotoxic.

3. *Reproductive and developmental toxicity*. A 2–generation rat reproduction study gave a no observed adverse effect level (NOAEL) of 100 ppm (8 mg/kg/bwt). Rat and rabbit developmental toxicity studies were negative at doses up to 30 mg/kg/bwt and 24 mg/kg/bwt, respectively.

4. *Subchronic toxicity*. Ninety–day feeding studies were conducted in rats and dogs. The NOAELs for these tests were 14 mg/kg/bwt/day (150 ppm) and 5 mg/kg/bwt/day (200 ppm), for the rat and dog studies, respectively.

5. *Chronic toxicity*. A 2–year rat feeding/carcinogenicity study was negative for carcinogenic effects under the conditions of the study and had a NOAEL of 100 ppm (5.7 mg/kg/bwt in males and 7.6 mg/kg/bwt in females for non–carcinogenic effects that included decreased body weight gain in females at 300 ppm and increased thyroid lesions in males at 300 ppm and females at 900 ppm. A 1–year dog feeding study indicated a NOAEL of 1,250 ppm (41 mg/kg/bwt). A 2–year mouse carcinogenicity study was negative for carcinogenic effects under conditions of the study and had a NOAEL of 1,000 ppm (208 mg/kg/day).

Imidacloprid has been classified under ''Group E'' (no evidence of carcinogenicity) by EPA's OPP/HED's Reference Dose (RfD) Committee. There is no cancer risk associated with exposure to this chemical. The RfD based on the 2–year rat feeding/carcinogenic study with a NOAEL of 5.7 mg/kg/bwt and 100-fold uncertainty factor, is calculated to be 0.057 mg/kg/bwt. The theoretical maximum residue contribution (TMRC) from published uses is 0.008358 mg/kg/bwt/day utilizing 14.7% of the RfD.

6. *Animal metabolism*. The metabolism of imidacloprid in rats was reported in seven studies. Data in these studies show that imidacloprid was rapidly absorbed and eliminated in the excreta (90% of the dose within 24 hours), demonstrating no biologically significant differences between sexes, dose levels, or route of administration. Elimination was mainly renal (70-80% o f the dose) and fecal (17-25%). The major part of the fecal activity originated in the bile. Total body accumulation after 48 hours consisted of 0.5% of the radioactivity with the liver, kidney, lung, skin and plasma being the major sites of accumulation. Therefore, bioaccumulation of imidacloprid is low in rats. Maximum plasma concentration was reached between 1.1 and 2.5 hours. Two major routes of biotransformation were proposed for imidacloprid. The first route included an oxidative cleavage of the parent compound rendering 6-chloronicotinic acid and its glycine conjugate. Dechlorination of this metabolite formed the 6-hydroxynicotinic acid and its mercapturic acid derivative. The second route included the hydroxylation followed by elimination of water from the parent compound.

7. *Metabolite toxicology*. Several metabolites of imidacloprid have been investigated for acute toxicity and genotoxicity. No evidence for genotoxicity was found, and acute toxicity values for all metabolites studied ranged from slightly more toxic to significantly less toxic than parent imidacloprid.

8. *Endocrine disruption*. The toxicology data base for imidacloprid is current and complete. Studies in this database include evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following short-term or long-term exposure. These studies revealed no primary endocrine effects due to imidacloprid.

C. Aggregate Exposure

1. *Dietary exposure*. Imidacloprid is a broad-spectrum insecticide with excellent systemic and contact toxicity characteristics with both food and non-food uses. Imidacloprid is currently registered for use on various food crops including seed treatments, tobacco, turf, ornamentals, buildings for termite control, and cats and dogs for flea control. Those potential exposures are addressed below:

i. *Food*. The EPA has determined that the reference dose (RfD) based on the 2 year rat feeding/carcinogenicity study with a NOAEL of 5.7 mg/kg/bwt and 100-fold uncertainty factor, is calculated to be 0.057 mg/kg/bwt. As published in the **Federal Register** June 12, 1996 (61 FR 29674) (FRL–5367–8) (petition to establish tolerances on leafy green vegetables (PP 5F4522/R2237)), the theoretical maximum residue contribution (TMRC) from published uses is 0.008358 mg/kg/bwt utilizing 14.7% of the RfD for the general population. For the most highly exposed subgroup in the population, non-nursing infants (less than 1 year old), the TMRC for the published tolerances is 0.01547 mg/kg/day. This is equal to 27.1% of the RfD.

The TMRC for corn is calculated to be 0.000055 mg/kg/bwt/day for the general population, which represents 0.1% of the RfD. The TMRC for the most highly exposed subgroup in the population, non-nursing infants is 0.000131 mg/kg/bwt/day, which represents 0.2% of the RfD. The TMRC for children ages 1 to 6 years is 0.000130 mg/kg/bwt/day, which represents 0.2% of the RfD, and for nursing infants is 0.000032 mg/kg/bwt/day, which represents 0.1% of the RfD. For children 7 to 12 years of age, the TMRC is 0.000098 mg/kg/bwt/day, which represents 0.2% of the RfD. Therefore, dietary exposure from field corn will not exceed the reference dose for any subpopulation (including infants and children).

ii. *Drinking water*. Although the various imidacloprid labels contain a statement that this chemical demonstrates the properties associated with chemicals detected in ground water, the Registrant is not aware of imidacloprid being detected in any wells, ponds, lakes, streams, etc. from its use in the United States. Imidacloprid is hydrolytically stable at pH 5 and 7 with photolytic degradation in water having a half-life of 4.2 hours. Under aerobic soil conditions in laboratory studies, imidacloprid has a half-life of 188 to >366 days. Under laboratory anaerobic aquatic conditions, the half-life was 27 days. Adsorption/desorption studies indicate that aged imidacloprid residues do not leach into the soil. Imidacloprid dissipates under actual field conditions with a half-life of 7 to 196 days. Imidacloprid remained in the top six inches of the soil in U.S. tests for the duration of nine of ten field dissipation studies. The presence of growing vegetation significantly increased the rate of degradation of imidacloprid. In studies conducted in

1995, imidacloprid was not detected in seventeen wells on potato farms in Quebec, Canada. In addition, ground water monitoring studies are currently underway in California and Michigan. Therefore, contributions to the dietary burden from residues of imidacloprid in water would be inconsequential.

2. *Non-dietary exposure*— i. *Residential turf*. Bayer Corporation has conducted an exposure study to address the potential exposures of adults and children from contact with imidacloprid treated turf. The population considered to have the greatest potential exposure from contact with pesticide treated turf soon after pesticides are applied are young children. Margins of safety (MOS) of 7,587 - 41,546 for 10 year old children and 6,859 - 45,249 for 5 year old children were estimated by comparing dermal exposure doses to the imidacloprid NOAEL of 1,000 mg/kg/day established in a 15 day dermal toxicity study in rabbits. The estimated safe residue levels of imidacloprid on treated turf for 10 year old children ranged from 5.6 - 38.2 g/cm^2 and for 5 year old children from 5.1 - 33.3 g/cm^2. This compares with the average imidacloprid transferable residue level of 0.080 g/cm^2 present immediately after the sprays have dried. These data indicate that children can safely contact imidacloprid-treated turf as soon after application as the spray has dried.

ii. *Termiticide*. Imidacloprid is registered as a termiticide. Due to the nature of the treatment for termites, exposure would be limited to that from inhalation and was evaluated by EPA's Occupational and Residential Exposure Branch (OREB) and Bayer Corporation. Data indicate that the Margins of Safety for the worst case exposures for adults and infants occupying a treated building who are exposed continuously (24 hours/day) are 8.0×10^7 and 2.4×10^8, respectively, and exposure can thus be considered negligible.

iii. *Tobacco smoke*. Studies have been conducted to determine residues in tobacco and the resulting smoke following treatment. Residues of imidacloprid in cured tobacco following treatment were a maximum of 31 ppm (7 ppm in fresh leaves). When this tobacco was burned in a pyrolysis study only two percent of the initial residue was recovered in the resulting smoke (main stream plus side stream). This would result in an inhalation exposure to imidacloprid from smoking of approximately 0.0005 mg per cigarette. Using the measured subacute rat inhalation NOAEL of 5.5 mg/m^3, it is apparent that exposure to imidacloprid from smoking (direct and/or indirect exposure) would not be significant.

iv. *Pet treatment*. Human exposure from the use of imidacloprid to treat dogs and cats for fleas has been addressed by EPA's Occupational and Residential Exposure Branch (OREB) who have concluded that due to the fact that imidacloprid is not an inhalation or dermal toxicant and that while dermal absorption data are not available, imidacloprid is not considered to present a hazard via the dermal route.

D. Cumulative Effects

No other chemicals having the same mechanism of toxicity are currently registered, therefore, there is no risk from cumulative effects from other substances with a common mechanism of toxicity.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data, it can be concluded that total aggregate exposure to imidacloprid from all current uses including those currently proposed will utilize little more than 15% of the RfD for the U.S. population. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. The TMRC from exposure to field corn for the general population, is 0.000055 mg/kg/bwt/day, which represents 0.1% of the RfD. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to imidacloprid residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of imidacloprid, the data from developmental studies in both rat and rabbit and a 2-generation reproduction study in the rat have been considered. The developmental toxicity studies evaluate potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates effects from exposure to the pesticide on the reproductive capability of mating animals through 2 generations, as well as any observed systemic toxicity.

FFDCA Section 408 provides that the EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal effects and the completeness of the toxicity database. Based on current toxicological data requirements, the toxicology database for imidacloprid relative to prenatal and postnatal effects is complete. Further for imidacloprid, the NOAEL of 5.7 mg/kg/bwt from the 2-year rat feeding/carcinogenic study, which was used to calculate the RfD (discussed above), is already lower than the NOAELs from the developmental studies in rats and rabbits by a factor of 4.2 to 17.5 times. Since a 100-fold uncertainty factor is already used to calculate the RfD, it is surmised that an additional uncertainty factor is not warranted and that the RfD at 0.057 mg/kg/bwt/day is appropriate for assessing aggregate risk to infants and children. Using the conservative exposure assumptions described above, EPA has concluded that the TMRC from use of imidacloprid from published uses is 0.008358 mg/kg/bwt/day utilizing 14.7% of the RfD for the general population. For the most highly exposed subgroup in the population, non-nursing infants (less than 1 year old), the TMRC for the published tolerances is 0.01547 mg/kg/day. This is equal to 27.1% of the RfD. The TMRC from exposure to field corn to non-nursing infants is 0.000131 mg/kg/bwt/day, which represents 0.2% of the RfD. The TMRC for children ages 1 to 6 years is 0.000130 mg/kg/bwt/day, which represents 0.2% of the RfD. For nursing infants, the TMRC is 0.000032 mg/kg/bwt/day, which is 0.1% of the RfD. For children ages 7 to 12 years, the TMRC is 0.000098 mg/kg/bwt/day, which is 0.2% of the RfD. Thus, it can be concluded that there is a reasonable certainty that no harm will result from additional exposure of infants and children.

F. International Tolerances

No CODEX Maximum Residue Levels (MRLs) have been established for residues of imidacloprid on any crops at this time.

[FR Doc. 01–370 Filed 1–4–01; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–989; FRL–6761–4]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–989, must be received on or before February 5, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–989 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Indira Gairola, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8375; e-mail address: gairola.indira@epa.gov.

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name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 21, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Morflex Inc.

PP 8E4966, PP 8E4967

EPA has received two pesticide petitions (PP 8E4966, PP 8E4967) from Morflex, Inc., 2110 High Point Road, Greensboro, North Carolina 27403. proposing, pursuant to section 408(d) of the (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for acetyl tributyl citrate (Citroflex® A4) and triethyl citrate (Citroflex®) when used as inert ingredients in or on growing crops, when applied to raw agricultural commodities (RAC) after harvest or when applied to animals (40 CFR 180.1001(c), and (e)). EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

Residue chemistry data are generally not required by EPA regarding decisions relevant to exemptions from the requirement of a tolerance for inert ingredient. However, applicable dietary modeling data and environmental fate data have been completed and is used for the assessments included in these petitions. Since Morflex is requesting an exemption from the requirement of a tolerance, an analytical method is not required.

B. Toxicological Profile

1. *Acute toxicity*—i. *Oral LD_{50} in rats.* Acetyl tributyl citrate (ATBC). The acute oral LD_{50} for ATBC is 31.5 grams/kilograms body weight (g/kg bwt). Rising doses of ATBC were administered to groups consisting of 5 rats per group of from 10.5 to 31.5 g/kg bwt. Some animals appeared sluggish, however, they recovered during the 21–day post dosing observation period. There were no mortalities at any dose.

ii. *Triethyl citrate (TEC).* The acute oral LD_{50} of TEC in rats was determined to be 7 milligrams/Liters (mL)/kg bwt. The technical material triethyl citrate was administered to groups of 5 rats by stomach tube at doses ranging from 5 to 15 mL/kg bwt. Signs of toxicity occurred within 1–hour and included weakness, depression, ataxia, hyperexcitability, unrest, urinary incontinence, irregular, and labored respiration, convulsions preceeding death in some animals. Mortalities occurred in 2 hours to 3 days, while survivors recovered within 15 hours to 4 days.

iii. *Oral LD_{50} in cats—ATBC.* The acute oral LD_{50} of ATBC was determined to be greater than 50 mL/kg bwt. The animals showed signs of slight nausea, and within a few hours they developed a diarrhea with oozing of the oily material from the rectum. The diarrhea subsided in less than 24 hours. There were no systemic toxicity signs as judged by the general appearance and behavior of the animals for periods up to 2 months.

iv. *TEC.* The acute oral LD_{50} of TEC was determined to be approximately 4 g/kg bwt in cats. TEC was administered by stomach tube to cats fasted for 24 hours in doses ranging from 1.1 to 10.8 g/kg bwt. Signs of toxicity consisted of nausea, vomiting, ataxia, weakness, muscle twitching, tremors, lowered body temperature, gasping, and shallow respiration, prostration, convulsions, respiratory failure and death. Mortalities occurred in about 2 hours to 2 days. Animals surviving recovered within 4 hours to 3 days depending upon the dose administered. Postmortem examinations showed no abnormalities of the thoracic abdominal organs related to the toxic signs.

v. *Intraperitoneal LD_{50} in mice—ATBC.* The acute intraperitoneal LD_{50} of ATBC was determined to be greater than 4g/kg bwt in Swiss Albino mice. The animals were observed for gross effects on appearance and behavior for 72 hours after dosing.

vi. *TEC.* The intraperitoneal LD_{50} of TEC was determined to be 1.75 g/kg bwt in Swiss Albino mice. Signs of toxicity included rapid loss of righting reflex without loss of consciousness, increased respiration rate, and clonic convulsions. Mortalities occurred during the first hour post dosing.

vii. *Intraperitoneal LD_{50} in rats.* The acute intraperitoneal LD_{50} of TEC in rats is 4.2 mL/kg bwt for females and 4.0 mL/kg bwt for males. Most deaths occurred within one hour post dosing following a depression of respiration and clonic convulsions. Pathological examinations of the animals that died indicated hemorrhage of the lung, pancreas and thymus, and marked congestion in the kidneys and liver.

viii. *Acute subcutaneous LD_{50} in rats.* The subcutaneous administration of TEC to rats resulted in LD_{50} of 6.7 mL/kg bwt in females and 6.6 mL/kg bwt in males. Mortalities typically occurred within 24 hours of dosing. Pathological examinations showed extensive hemorrhage in the lungs, and thymus, loss of hair, edema, and crust formation at injection sites. In surviving animals, at the end of the 14–day observation period, necrotic ulcers were noted at injection sites.

ix. *Acute dermal LD_{50} in guinea pig and rabbit.* The dermal LD_{50} of TEC was determined to be greater than 11.4 g/kg bwt in guinea pigs and greater than 5.7 mg/kg bwt in rabbits.

x. *Acute inhalation LC_{50} in rats.* The 6–hour inhalation LC_{50} of TEC in rats was determined to be approximately 1,300 ppm. In this study, groups of rats were exposed to vaporized TEC for 6 hours at concentrations between 1,300 and 3,500 ppm.

xi. *Skin irritation in rabbits—ATBC.* ATBC was found to be non-irritating to rabbit skin when applied as the undiluted technical material. The abdomens of 3 male Albino rabbits were clipped and 1 mL of ATBC was applied

to the intact skin daily for 4 days. The animals were observed for a period of 36 hours after the last application. There was no evidence of irritation.

xii. *TEC*—TEC was determined to be non-irritating to rabbit skin. Undiluted TEC was applied to intact or abraded rabbit skin for 24 hours under occlusion before scoring for irritation.

xiii. *Guinea pig sensitization—ATBC.* ATBC was found to be non sensitizing to the skin of Guinea pigs following the method Magnusson and Kligman's Guinea pig maximumization test. Sensitization was induced in guinea pigs by intradermal injections of the test substance and complete Freunds Adjuvant. The induction process was supplemented 7 days later by application of ATBC to the shoulder injection sites under occlusion. Fourteen days later the animals were challenged by occluded patches. Challenges were repeated after 1–week. Evaluations for contact sensitization were performed at 24 and 48 hours after patch removal.

xiv. *TEC.* TEC was found to be a strong sensitizer in 9 of 10 Guinea pigs after the first challenge and in all 10 Guinea pigs after the second challenge. TEC was tested for the potential to induce contact dermatitis according to the Magnusson-Kligman's Guinea pig maximization test method. Sensitization was induced by intradermal injections of both test substance and Freunds Adjuvant and the induction process supplemented 7 days later by the test substance applied to the shoulder injections sites under occlusion. The animals were challenged by occluded patch 14 days later.

xv. *Human repeated insult patch test—ATBC.* ATBC was evaluated in 59 human subject panelists (males and females) in the repeated insult patch test of Draize. The test substance was found not to induce dermal irritation or contact sensitization. For this test, each of the 59 panelists received a test patch (20x20 cm) moistened with 0.4 mL of ATBC to the upper arms 3 times a week for 3 weeks. Patches were secured in place for 24 hours before removal. Duplicate challenges were made 2 weeks after the final serial applications, 1 set of patches to original sites and 1 set to adjacent sites. Patch sites were scored prior to patch applications and scored at 48 and 96 hours after applications.

xvi. *TEC.* Triethyl citrate was tested in an adaptation of the repeat insult patch test of Draize in 59 human subject panelists (males and females). A quantity of 0.4 mL of undiluted TEC was applied to each test patch prior to application. Patches were applied to each panelist 3 times a week for 3 consecutive weeks. Instructions were given to each panelist to keep the patches dry and to remove them 24 hours after application. Duplicate challenge applications were made 2 weeks after the final serial applications; 1 at the original site and 1 at an adjacent site. The patch sites were evaluated at 48 and 96 hours after application. There was no evidence of dermal irritation and no reactions suggestive of contact sensitization in any of the panelists.

2. *Genotoxicty*—i. *ATBC. Ames Salmonella/microsome reverse mutation assay.* ATBC did not exhibit mutagenic activity in the Ames assay with or with metabolic activation. ATBC was tested in a preincubation modification of the Ames assay with *Salmonella typhimurium* tester strains TA98, TA100, TA1535, and TA1537. Tests were performed in all strains, both with and without metabolic activation using S–9 rat liver systems. Assays were repeated twice in all strains. Another test was performed with ATBC using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538, with and without metabolic activation using rat liver S–9 mix or hamster liver S–9 mix. Results were negative for mutagenicity in all 5 strains in the presence of both rat and hamster liver S–9 mix and in the absence of metabolic activation.

ii. *Mouse lymphoma mutagenesis assay.* ATBC produced a negative response in cultures with and without metabolic activation using Arochlor induced rat liver S–9 mix. The test article was assayed for mutagenic potential using thymidine kinase locus of L51784 TK+/-mouse lymphoma cells.

iii. *In vitro chromosomal aberration assay in rat lymphocytes.* ATBC did not exhibit clastogenic activity (increases in chromosomal aberrations) in cultured rat lymphocytes as compared with negative controls, either in the presence or absence of metabolic activation. ATBC was evaluated in a cytogenic assay using rat lymphocyte cells with and without rat liver S–9 mix metabolic activation. Frequencies of chromosomal aberrations, based upon mitotic indicies were determined from ATBC treated cultures and were found not to be significantly different than negative controls. Based upon the results of this study, ATBC did not exhibit clastogenic activity in cultured rat lymphocytes.

iv. *Chinese hamster ovary cell/hypoxanthine-guanine-phosphoribosyl transferase (CHO/HGPRT) forward mutation assay.* In this forward mutation assay, ATBC in 2 independent tests, did not induce a mutagenic response. ATBC was evaluated both in the absence and presence of rat liver S–9 mix metabolic activation. The forward mutation frequencies of ATBC treated cultures were not significantly different from those of negative controls, indicating no mutagenic response.

v. *Unscheduled DNA synthesis in rats.* ATBC did not induce unscheduled DNA systhesis (UDS) in livers from rats treated with commercial material at a dose of 10 mL/kg.

3. *Genotoxicity—TEC.* Microbial assays, *Salmonella typhimurium and Saccaromyces cerevisiae.* TEC was not mutagenic in *Salmonella typhimurium* strains TA1535, TA1537, and TA1538 and in *Saccharomyces cerevisiae* strain D4, without metabolic activation, and with metabolic activation using S–9 mix from male mouse, rat and monkey livers. Plate tests and suspension tests were performed with the indicator strains of both test organisms. Based upon cell toxicity studies, concentrations from 0.4 to 1.7% were employed as the dose levels in the mutagenicity assays. Results were negative for mutagenicity with both bacteria and yeast organisms, with both the plate and suspension tests, with and without metabolic activation.

4. *Reproductive and developmental toxicity*—i. *ATBC. A 2–generation reproduction study in rats.* A 2–generation reproduction study conducted with ATBC in Sprague Dawley rats resulted in a no observed effect level (NOEL) of 100 milligrams/kilogram body weight mg/kg bwt/day based upon the lowest observed effect level (LOEL) of 300 mg/kg bwt/day for decreased maternal bwts gains and water consumption and reduced bwts and slightly higher mortalities among their offspring. This 2–generation reproduction study was conducted in Sprague Dawley rats with ATBC at dietary levels of 100, 300, or 1,000 mg/kg bwt/day to evaluate the potential effects on reproductive performance and on the survival and growth of offspring through 2–generations. In this study, 4 groups of male and female rats received control or 1 of the 3 dietary levels of ATBC continuously. Prior to mating, males were treated for 77 days and females for 21 days. After mating, males of the F_0 generation were removed and pregnant females were continued on diet through gestation, delivery and lactation. Subsequent F_1 offspring were maintained on the same diets as their parents for at least 10 weeks prior to mating within groups. The resulting F_2 generation litters were also maintained on the same diets as their parents for at least 14 days.

ii. *TEC. Developmental toxicity in the developing chicken embryo.* Treatment

of chicken embryos with TEC resulted in a negative teratogenic response. In this study, TEC was dissolved in ethanol to deliver a maximum of 10 mg per egg. The test substance in solution was administered by 2 routes, into the yolk and through the air sac. For each route, eggs were treated at 2 stages of incubation: preincubation (0–hour), and at the fourth day (96– hour).

5. *Subchronic toxicity*—i. *ATBC.* Fourteen–day range finding dietary toxicity in rats. In a 14–day range finding feeding study with ATBC, the NOEL was determined to 1,000 mg/kg bwt/day. In this study ATBC was administered in the diet at concentrations of 1%, 2.5% and 5% equivalent to doses of 1,000, 2,700 and 5,000 mg/kg bwt/day. Observations included clinical signs of toxicity, bwts, food intake, test substance intake, complete gross pathology including organ weights, and histopathologic examinations of livers. Food intake was initially decreased in all test groups, however, differences persisted in only among males of the 5,000 mg/kg bwt/day group. The initial differences are likely related to the unpalatability of the diet. Body weights were significantly lower among animals of the 2,700 mg/kg bwt/day and 5,000 mg/kg bwt/day treatment groups throughout the study. Organ weight determinations resulted in significantly increased relative liver weights among high dose females. Upon microscopic examinations of the livers there were increased cytoplasmic eosinophilia and a concomitant reduction of glycogen content of hepatocytes in periportal areas from animals of the 2,700 mg/kg bwt/day and 5,000 mg/kg bwt/day dose groups.

ii. *Ninety–day dietary toxicity in rats.* The results of a 90–day feeding study with ATBC resulted in a NOEL of 300 mg/kg bwt/day based upon the LOEL of 1,000 mg/kg bwt/day for minor changes is relative liver weights, liver enzymes and bilirubin levels. This study was conducted Sprague Dawley rats receiving dietary levels of ATBC of 0, 100, 300, or 1,000 mg/kg bwt/day for 90 days. All animals were observed daily for clinical signs of toxicity. Ophthalmoscopic observations were conducted in all animals of the highest dose group at pretest, and just prior to the treatment period. Body weights were recorded daily for all animals on day 1 of treatment and weekly thereafter. Food consumption was measured over 1 week periods, while water consumption was measured in each animal during the first and eleventh week of dosing. The results of clinical chemistries, hematology and urinalysis were recorded and complete necropsies with histological examinations were performed. A few statistically significant differences were noted between animals of the high dose group (1,000 mg/kg bwt/day) and controls including increased relative liver weights, liver enzymes, and bilirubin levels. However, there were no histopathological findings indicative of treatment related effects.

iii. *TEC. Subchronic oral* toxicity in mice. TEC was evaluated for subchronic toxicity in a group of 20 mice receiving 350 mg/kg bwt/day of commercial grade test substance (purity >99%) in 3% acacia intraperitoneally, daily for 14 consecutive days. A control group consisting of the same number of mice received 3% acacia daily under the same schedule. Body weight gains of TEC treated mice were significantly lower as compared with controls by day 7. There were no significant differences in red and white blood cell counts, clotting times, and hemoglobin levels between treated and control mice. Under the conditions of the study, the LOEL was established at 350 mg/kg bwt/day, when given intraperitoneally for 14 days.

iv. *Subchronic dietary toxicity in rats.* In an 8 week dietary feeding study in rats with TEC, the NOEL was established at 4 g/kg bwt/day. Groups of approximately 4 males and 4 females were administered TEC in the diet at concentrations of 0, 0.5, 1.0, or 2.0%. These dietary concentrations were estimated to be equivalent to 0, 1, 2, or 4 g/kg bwt/day TEC. TEC administered daily in the diet at doses up to approximately 1/2 of the rat oral LD_{50} had no significant effect on growth. Blood counts including red and white blood cell counts, differential cell counts were not significantly among treatment and control groups. There were no, gross findings in thoracic or abdominal organs at necropsy. Histological sections of organs, including the heart, lungs, gastrointestinal tract, liver, pancreas, spleen, and kidneys, revealed no differences between treatment and control animals.

v. *Subchronic toxicity in dogs.* In this study, 4 dogs were given daily doses of 2.5 to 3.5 mL/kg bwt/day (2,840 to 3,975 mg/kg bwt/day) as rising doses for 7 to 12 weeks. The study report indicates bwt gains were normal as were results of urinalysis and serum chemistries. Hematology results suggested a tendency to anemia. Organ weights were normal except for one abnormally heavy liver. At these doses severe and widespread liver pathology was evident. Other organs were reportedly normal. As the purpose of the study was to determine the toxic dose for repeated administrations of TEC, the NOEL was not established.

6. *Chronic toxicity*—i. *ATBC. 2–year chronic toxicity in rats.* A 2–year chronic toxicity study conducted with ATBC in Sherman rats at dietary concentrations of 0, 200, 2,000, or 20,000 ppm (equivalent to 0, 10, 100, or 1,000 mg/kg bwt/day) resulted in a NOEL of 1,000 mg/kg bwt/day. Animals were observed for physical appearance and behavior throughout the study as were individual bwts. All animals that died and those sacrificed at the end of the study were examined for gross and histological changes. No differences in behavior or physical appearance was noted among treated and control animals. There were no statistically significant differences between the growth of animals treated with ATBC and controls. There were no statistical differences in mortalities among treatment and control animals. Inflammatory disease of the lungs was the most common finding at autopsy, however, there was no treatment related differences. There were no differences in tumor frequencies among treatment and control animals. There was no reported evidence of effects on the endocrine system.

ii. *TEC. 2–year chronic dietary toxicity in rats.* In this study, TEC administered to rats for 2 years via dietary administration resulted in no significant effects at the highest dose tested, equivalent to 1,500 mg/kg bwt/day. Sprague Dawely rats (15 per sex per dose group) were fed diets containing TEC at concentrations of 0, 0.33, 1.0, or 3.0% for 2 years. These dietary concentrations are estimated to be equivalent to 0, 165, 500, or 1,500 mg/kg bwt/day. Clinical observations were made daily and individual bwts were measured weekly. Blood and urine evaluations were conducted at specified intervals. Scheduled interim sacrifices of animals included macroscopic examinations of thoracic and abdominal organs and microscopic examinations of the kidney and liver tissues. All animals that died spontaneously during the study, as well as all animals remaining at the termination of study (1 or 2 years), were examined by a pathologist. At terminal sacrifice, microscopic examinations were made of kidney, liver, heart, lungs, spleen, stomach, small intestine, adrenals, ovaries, uterus, testes, and seminal vesicles. There were transiently lower bwts among males of the high dose group animals, possibly related to the unpaletibility of the diet. There were no significant differences observed between treated and control groups for the

following blood examinations: hemoglobin, erythrocyte count, non-protein nitrogen, and sugar determination. Urine tests for reaction, albumin, reducing substances, and microscopic evaluation were all considered to be normal. Terminal and interim autopsies disclosed no findings that were significant or attributable to TEC treatment. Size and weight of organs of the principal tissues at the time of autopsy were unremarkable. There were no significant differences between treated and control animals in comparison to the pathological findings.

iii. *Six months dietary toxicity in dogs*. In a 6 month dietary toxicity study in dogs, TEC did not exhibit any toxic effects and the NOEL is greater than 280 mg/kg bwt/day the highest dose tested (HDT). Groups of 4 Beagle or Beagle type dogs (males and females) were administered 6 days per week for 6 months at dietary levels of TEC equivalent to 55 or 280 mg/kg bwt/day. The dogs were observed daily, weighed weekly and urinalysis were conducted at 3 and 6 months after initiation of the study. Blood samples were taken at 2, 4, and 6 months after initiation of dosing for hematological examinations. Dogs were sacrificed at the end of the in-life dosing phase and necropsied. Body weight gain and clinical observations were normal throughout the study. No significant changes or abnormalities were reported in hematology, serum chemistry or urinalysis during the course of the study. Gross examinations of major organs and organ weights at necropsy were normal. Histopathologic examinations of the major organs did not show any abnormalities.

7. *Animal metabolism*—i. *ATBC*. Metabolism and disposition of acetyl tributyl citrate in male Sprague Dawley rats. The metabolism of ATBC using ^{14}C–ATBC in rats receiving single oral doses of 70 mg/kg. ATBC was determined to be rapidly absorbed and excreted with an elimination half-life of 3.4 hours. Greater than 98% of administered ^{14}C was achieved via urine, feces and in expired air 48 hours after dosing. Urinary metabolites identified in this study include acetyl citrate, monobutyl citrate, acetyl monobutyl citrate, dibutyl citrate, and acetyl dibutyl citrate.

ii. *Metabolism of acetyltributylcitrate (ATBC) and tributylcitrate (TBC) in human serum and rat liver homogenates*. The metabolism of ATBC and the intermediate deacetylated metabolite tributylcitrate (TEC), was studied *in vitro* using human serum and rat liver homogenates. At a concentration of 100 µg/mL in human serum, ATBC was found to undergo extensive metabolism with a half-life of approximately 32 hours. Also, at a concentration of 100 µg/mL in rat liver homogenate, ATBC was found to undergo extensive and complete metabolism with a half-life of approximately 10 minutes. There is very little or no emonstrable TBC in the 2 test systems because of the rapid further metabolism of this intermediate metabolite. The metabolic half-life of TBC in human serum and rat liver homogenate was approximately 4 hours and a few seconds, respectively. These studies confirm the ready and complete conversion of ATBC and TBC via ester hydrolysis to acetic acid, citric acid and butanol. Butanol would be expected to undergo oxidation to butyric acid and further metabolism by b-oxidation.

iii. *TEC. Absorption, distribution, metabolism and excretion of tiethyl citrate in the rat*. Following a single oral 2 mg/kg dose of ^{14}C–TEC in rats, a peak blood concentration of about 1.48 µg eq./g blood was achieved at 15 minutes post-administration, blood concentration rapidly decreased to about 0.05 µg eq./gm blood after 1 hour and was barely detectable after 24 hours. Tissue distribution was examined after single oral administration of a 2 mg/kg dose of ^{14}C–TEC to rats. At 15 minutes post-administration, relatively high ^{14}C concentrations were found in the didney (37.81+ 5.02 µg eq./g tissue), stomach (10.00+ 3.53 µg eq./g tissue), small intestines including contents (10.65 + 3.15 µg eq./g tissue) and liver (4.40 + 0.77 µg eq./g tissue). By 24 hours after dosing, the ^{14}C concentrations detected in most tissues had decreased to near the detection limit (0.01 µg eq./g tissue), with the exception of the large intestine including contents. Cumulative urinary, fecal and expiratory excretions of ^{14}C–TEC were 93, 0.2 and 1%, respectively, 8 hours after administration of a single 2 mg/kg dose of ^{14}C–TEC. At 120 hours after dosing, the total ^{14}C excretion of urine, feces and expiration had reached 99%. Metabolism of ^{14}C–TEC was investigated using the 24–hour urine of rats after a single oral administration of a 2 mg/kg dose. Three major metabolites were separated by thin-layer chromatography and identified using gas chromatography (GC/MS). Two of the metabolites were isomers of diethyl citrate and 1 was found to be monoethyl citrate.

8. *Endocrine disruption*. Chronic and reproductive toxicity data conducted with ATBC and chronic toxicity data conducted with TEC are without adverse effects to reproductive or the endocrine system. Also, the compounds do not share structural similarities with currently known or chemicals suspected to have endocrine disruptive properties.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. ATBC and TEC are currently classified as generally recognized as safe (GRAS) for use in foods and food packaging, cosmetics, pharmaceuticals, and as plasticizers for consumer and packaging products. The current petition, requests the exemption from tolerances for these compounds when used as inert ingredients in agricultural formulations for use on growing crops for post harvest applications to food crops and applications to animals. Although residue data are generally not required for inert ingredient exemptions from tolerances, Morflex, Inc. has developed worst case assumptions using Novigen Sciences Dietary Exposure Evaluation Model (DEEM) with data inputs based upon the model of Kenaga and Hoergers: Maximum Expected Residues on Vegetation. The Kenega nomogram is used to predict maximum residue levels present on day 0 following different application rates of a chemical to 1 of 6 different categories of plants or plant parts. The 3 basic features of the Kenaga nomogram-catagories of plants and plant parts, maximum predicted residue levels, and a linear dose-residue relationship. Crops and crop groups selected for this analysis include the following: leafy vegetables (succulent or dried), fruiting vegetables, cucurbit vegetables, citrus fruits, pome fruits, stone fruits, berries, cereal grains, grapes, and bananas. The reference dose chosen for this analysis, was derived from the NOEL resulting from a chronic rat (2–year) study conducted with ATBC. This study was conducted at dietary concentrations of 0, 200, 2,000, and 20,000 ppm equivelant to 0, 10, 100, and 1,000 mg/kg bwt/day of ATBC. No effects were reported up to the HDT. Therefore, for the purposes of this assessment, a chronic reference dose (RfD) of 10 mg/kg bwt/day was used. The chronic RfD includes an uncertainty factor of 100 to account for intra-species and inter-species variations. Food consumption data from the United States Department of Agriculture (USDA) CSFII conducted in 1994 through 1996, were used to estimate dietary exposure. The levels of ATBC and TEC can vary depending upon the percent of ATBC and TEC in the formulation and/or the application rate of the product. For purposes of this screening level assessment, an application rate of 3 pounds per acre of ATBC or TEC was assumed. Also, no adjustment was made for percent crop

treated and all commodities contain residues at predicted day zero levels. For this screening level assessment with an application rate of 3 pounds ATBC or TEC per acre, the following 0–time level residues are predicted from the nomogram: leafy vegetables–375 ppm, legume vegetables–36 ppm, fruiting vegetables, cucurbit vegetables, citrus fruits, pome fruits, stone fruits, berries, cereal grains, grapes, and bananas–21 ppm.. Using the above modeling parameters, chronic exposure was estimated for the overall U.S. population and 25 population subgroups. Chronic exposure for the overall U.S. population was estimated to be 0.492873 mg/kg bwt/day, representing 4.9% of the RfD. The exposure estimate for the most highly exposed population subgroup, children 1-6 years of age, was 0.984312 mg/kg bwt/day, or 9.8%.

ii. *Drinking water*. Based upon the chemical and physical properties, and the environmental fate characteristics, ATBC and TEC are not expected to persist environmentally, nor result in significant concentrations in drinking water sources.

2. *Non-dietary exposure*. ATBC and TEC are currently used in non-food use pesticide formulations, as well as in food, food packaging, cosmetics, medical devices and pharmaceuticals, and as plasticizers.

D. Cumulative Effects

Cumulative effects are not expected since ATBC and TEC are rapidly degraded to natural substances.

E. Safety Determination

1. *U.S. population*. Based upon the dietary residue exposure analysis using the Kenega nomogram, the most sensitive population, children 1–6 years, was 0.984312 mg/kg bwt/day or 9.8% of the RfD for the crops and crop groups used in this assessment. Results of a 2–generation reproduction study with ATBC did not reveal developmental or reproduction effects at doses up to 100 mg/kg bwt/day. Also, based on the absence of pup toxicity up to the dose level (1,000 mg/kg bwt/day) producing maternal effects, there is no evidence of special post-natal sensitivity to infants and children. It is concluded that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to acetyl tributyl citrate (ATBC) or triethyl citrate (TEC) when used as inert ingredients in agricultural formulations of pesticides.

2. *Infants and children*. No embryotoxic, developmental, or teratogenic effects have been associated with acetyltributyl citrate (ATBC) or triethyl citrate (TEC).

F. International Tolerances

Morflex Inc. is unaware of any International tolerances or CODEX maximum residue limits (MRL's) for acetyltributyl citrate (ATBC) or triethyl citrate (TEC) on any crop or livestock commodities.

[FR Doc. 01–369 Filed 1–4–01; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6930–2]

Notice of Tentative Approval, Request for Comments and Solicitation of Requests for a Public Hearing for Public Water System Supervision Program Revision for the Commonwealth of Virginia

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Tentative Approval and Solicitation of Requests for a Public Hearing.

SUMMARY: Notice is hereby given in accordance with the provision of section 1413 of the Safe Drinking Water Act as amended, and the rules governing National Primary Drinking Water Regulations that the Commonwealth of Virginia has revised its approved Public Water System Supervision Primacy Program. Specifically, Virginia has adopted Consumer Confidence Report regulations requiring annual drinking water quality reports from community water suppliers. EPA has determined that these regulations are no less stringent than the Federal provisions and satisfy the requirements of the Federal regulations. Therefore, EPA has decided to tentatively approve the program revisions. All interested parties are invited to submit written comments on this determination and may request a public hearing.

DATES: Comments or a request for a public hearing must be submitted by February 5, 2001. This determination shall become effective on February 5, 2001 if no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his own motion, and if no comments are received which cause EPA to modify its tentative approval.

ADDRESSES: Comments or a request for a public hearing must be submitted to Patti Kay Wisniewski, Drinking Water Branch (3WP22), U.S. Environmental Protection Agency Region III, 1650 Arch Street, Philadelphia, PA 19103–2029.

All documents relating to this determination are available for inspection between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, at the following offices:

- Drinking Water Branch, Water Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103–2029; and
- Virginia Department of Health, Division of Water Supply Engineering, 1500 East Main Street, Richmond, Virginia 23218.

FOR FURTHER INFORMATION CONTACT: Patti Kay Wisniewski at the Philadelphia address given above; telephone (215) 814–5668 or fax (215) 814–2318.

SUPPLEMENTARY INFORMATION: All interested parties are invited to submit written comments on this determination and may request a public hearing. All comments will be considered, and, if necessary, EPA will issue a response. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial request for a public hearing is made by February 5, 2001, a public hearing will be held. A request for public hearing shall include the following: (1) The name, address, and telephone number of the individual, organization, or other entity requesting a hearing; (2) a brief statement of the requesting person's interest in the Regional Administrator's determination and of information that the requesting person intends to submit at such a hearing; and (3) the signature of the individual making the request; or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

Dated: December 27, 2000.

Bradley M. Campbell,

Regional Administrator, EPA, Region III.

[FR Doc. 01–362 Filed 1–4–01; 8:45 am]
BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission

December 20, 2000.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as

required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before February 5, 2001. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Judy Boley, Federal Communications Commission, room 1–C804, 445 12th Street, SW., DC 20554 or via the Internet to *jboley@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judy Boley at 202–418–0214 or via the Internet at *jboley@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0966.

Title: Sections 80.385, 80.475, and 90.303, Automated Marine Telecommunications Service (AMTS).

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households and businesses or other for-profit.

Number of Respondents: 20.

Estimated Time Per Response: .50 hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Total Annual Burden: 10 hours.

Total Annual Cost: N/A.

Needs and Uses: The reporting requirements are necessary to require licensees of Automated Maritime Telecommunications System (AMTS) stations to notify TV stations and two organizations (the American Radio Relay League (ARRL), and Interactive Systems, Inc.) that maintain databases of AMTS locations for the benefit of amateur radio operators of the location of AMTS fill-in stations. Amateur radio operators use some of the same frequencies (219–220 MHz) as AMTS stations on a secondary, non-interference basis for digital message forwarding systems. Reporting requirements are necessary to require amateurs proposing to operate within close proximity of an AMTS station to notify the AMTS licensee as well as the ARRL. The information is used to update databases concerning AMTS locations for the benefit of amateur radio operators. If the collection of this information was not conducted, the database would become inaccurate and the ability to avoid interference problems would deteriorate.

Federal Communications Commission.

William F. Caton,

Deputy, Secretary.

[FR Doc. 01–278 Filed 1–4–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted to OMB for Review and Approval

December 15, 2000.

SUMMARY: The Federal Communications Commissions, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before February 5, 2001. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *lesmith@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418–0217 or via the Internet at *lesmith@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0761.

Title: Closed Captioning of Video Programming.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business and other for-profit entities; and Individuals or households.

Number of Respondents: 1,425.

Estimate Time Per Response: 30 mins. to 5 hrs.

Frequency of Response: On occasion reporting requirement; Third party disclosure.

Total Annual Burden: 2,013 hours.

Total Annual Costs: $19,000.

Needs and Uses: The FCC's Report and Order, FCC 97–279, adopted rules and implementation schedules for the closed captioning of video programming, pursuant to Section 305 of the Telecommunications Act of 1996, which added Section 713, Video Programming Accessibility, to the Communications Act of 1934, as amended. The requirements set forth in Section 713 are intended to ensure that video programming is accessible to individuals with hearing disabilities through close captioning, regardless of the delivery mechanism used to reach consumers. Pursuant to Section 713, the FCC established phase-in schedules to increase the amount of closed captioned programming. The rules also provided procedures for entities to use to request exemptions of the closed captioning requirements base on an undue burden standard.

Furthermore, they detailed a complaint process for viewers to use for the enforcement of closed captioning requirements.

Federal Communications Commission.

William F. Caton,

Deputy, Secretary.

[FR Doc. 01–277 Filed 1–4–01; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1682]

Agency Information Collection Activities; Proposed Collection; Comment Request; Radioactive Drug Research Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements related to radioactive drugs used in research.

DATES: Submit written or electronic comments on the collection of information by March 6, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA, (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Radioactive Drug Research Committee—21 CFR 361.1 (OMB Control Number 0910–0053)—Extension

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic informational research. The regulations in § 361.1 (21 CFR 361.1) set forth specific regulations regarding the establishment and composition of the Radioactive Drug Research Committees and their role in approving and monitoring research studies utilizing radiopharmaceuticals. No study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA-approved Radioactive Drug Research Committee (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

The regulations in § 361.1(c)(2) require that each Radioactive Drug Research Committee shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each Radioactive Drug Research Committee shall submit an annual report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the Radioactive Drug Research Committee, and for each study conducted during the proceeding year, using FDA Form 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under section 361.1(d)(8), the investigator shall immediately report to the Radioactive Drug Research Committee all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)). Types of research studies not permitted under this regulation are also specified, and include those ''intended for (the) immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial).'' These studies require filing of an investigational new drug application under 21 CFR 312.1 and the associated information collections are covered under OMB Control No. 0190–0014, which expires December 31, 2002.

The primary purpose of this collection of information is to determine if the research studies are being conducted in accordance with required regulations. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation and/or safety risks. Respondents to this information collection are the chairperson(s) of each individual Radioactive Drug Research Committee,

investigators, and participants in the studies.

The source of the burden estimates was a phone survey of three committee chairpersons who were selected from different geographical areas and of varying levels of Radioactive Drug Research Committee membership and activities. These chairpersons were asked for their assessment of time expended, cost, and views on completing the necessary reporting forms.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
361.1(c)(3)	FDA 2914	96	1.0	96	1	96
361.1(c)(3)	FDA 2915	63	5	315	3.5	1,103
361.1(d)(5)		63	5	315	0.1	31
361.1(d)(8)		63	5	315	0	0
Total						1,230

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	Form	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
361.1(c)(2)	FDA 2914 and 2915	96	1 per quarter 4 per year	10	960
Total					960

Dated: December 27, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–262 Filed 1–4–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1425]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Human Tissue Intended for Transplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments on the collection of information by February 5, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Tissue Intended for Transplantation—Part 1270 (21 CFR Part 1270)—(OMB Control Number 0910–0302)—Extension

Under section 361 of the Public Health Service Act (42 U.S.C. 264), FDA issued regulations to prevent the transmission of human immunodeficiency virus 1 and 2, hepatitis B, and hepatitis C through human tissue intended for transplantation. The regulations provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet standards intended to ensure appropriate screening and testing of human tissue donors and to ensure that records are kept documenting that the appropriate screening and testing have been completed. Section 1270.31(a) and (b) require written procedures to be prepared and followed for: (1) All significant steps in the infectious disease testing process, and (2) all significant steps in reviewing the relevant medical record of the donor. Any deviation from the written procedures are to be recorded and justified. Section 1270.33(a) requires records to be maintained concurrently with the performance of each significant step in infectious disease screening and testing of human tissue donors. Section 1270.33(f) requires records be retained regarding the determination of the suitability of the donors and such records required under §1270.21. Section 1270.33(h) requires all records be retained at least 10 years beyond the date of transplantation, distribution, disposition, or expiration of the tissue, whichever is latest. Section 1270.35 requires specific records to be maintained to document: (1) The results and interpretation of all required infectious disease tests and results, (2) the identity and relevant medical records of the donor, (3) the receipt and distribution of human tissue, and (4) the destruction or other disposition of human tissue.

Respondents to this collection of information are manufacturers of human tissue-based products. The following estimated numbers of establishments, donors, and products, which are based on information provided by industry associations, including the Eye Bank Association of America 1999 Eye Banking Statistical Report, revise the numbers from the 60-day notice (65 FR 48245, August 7, 2000). There are approximately 224 tissue establishments currently in operation, 110 conventional tissue banks and 114 eye tissue banks. There are an estimated total of 750,000 conventional tissue products and 86,900

eye tissue products manufactured per year. In addition, there are an estimated 20,000 donors of conventional tissue and 43,800 donors of eye tissue each year, with an estimated 45,500 and 14,600 unsuitable donors of conventional tissue and eye tissue, respectively.

On July 29, 1997 (62 FR 40429), FDA issued a final rule on human tissue intended for transplantation, part 1270, which finalized the interim rule implemented on December 14, 1993 (58 FR 65514). At that time, accredited members of the American Association of Tissue Banks (AATB) and the Eye Bank Association of America (EBAA) were adhering to the standards of those organizations, which were comparable to recordkeeping requirements in part 1270, and were thus already in compliance with the interim rule. In 1997, we estimated that approximately 99 percent of the 170 tissue establishments (60 conventional tissue banks and 110 eye banks) then in operation, or 168 establishments, were accredited members of AATB and EBAA. Therefore, recordkeeping by these 168 establishments is excluded from the burden estimates as usual and customary business activities (5 CFR 1320.3(b)(2)). The recordkeeping burden below, thus, is estimated for the remaining 56 establishments (224 - 168 = 56).

The requirement for the development of written procedures under § 1270.31(a) and (b) is considered an initial one-time burden. FDA assumes that all current tissue establishments have developed written procedures in compliance with part 1270. FDA also assumes that no new tissue banks will begin operation in the next 3 years. Therefore, the information collection burden under § 1270.31(a) and (b) is for the general review and update of written procedures, and the recording and justifying of any deviations from the written procedures, which we estimate to be an annual average of 24 hours for all written procedures per establishment. The information collection burden for maintaining records concurrently with the performance of each significant screening and testing step and for retaining records for 10 years under § 1270.33(a), (f), and (h) include documenting the results and interpretation of all required infectious disease tests and results and the identify and relevant medical records of the donor required under § 1270.35(a) and (b). Therefore, the burden under these provisions is calculated together in table 1 of this document. The recordkeeping estimates below for the number of total annual records and hours per record are based on information provided by industry and FDA experience.

In the **Federal Register** of August 7, 2000 (65 FR 48245), FDA published a 60-day notice requesting public comment on the information collection provisions. One letter of comment was received in response to the 60-day notice.

The comment stated that the requirements for written procedures represent ongoing, not one-time, costs, in part because written procedures must be periodically reviewed and updated.

FDA agrees that the review and update of written procedures are part of the information collection burden associated with the recordkeeping requirements and revised estimates are reflected in table 1 of this document.

The comment stated that there are costs associated in preparing different formats to comply with FDA requirements and tissue bank association standards.

The provisions in part 1270 do not require that data be prepared in a specified recordkeeping format. Separate records for the same or similar information are not necessary.

The comment also noted that there are other additional costs and recordkeeping burdens associated with an FDA inspection in that an establishment must review its records at that time.

The regulations do not impose any additional recordkeeping requirements during inspections. Costs incurred by establishments during an inspection are beyond the scope of this PRA analysis.

The comment was also concerned that the regulations created a burden by necessitating the direct observation of all testing performed by a contract laboratory.

The requirement to have written procedures for and to document all significant steps in the infectious disease testing process does not require an establishment to directly observe the performance of all medical tests to ensure compliance with part 1270. A tissue establishment may have a written procedure for ensuring that contract laboratories comply with the testing requirements in part 1270, such as the requirement that laboratories are using FDA licensed tests, are Clinical Laboratory Improvement Amendments certified, and follow manufacturers instructions for performing the required tests. For example, an establishment may write a procedure that would include performance of a periodic audit or to review a laboratory's standard operating procedures (SOP's) to ensure compliance with part 1270.

The comment also discussed the regulation's economic impacts, such as equipment costs and general operating costs, which go beyond the scope of information collection provisions. However, FDA will consider such issues when reviewing comments to the proposed rule on suitability determination for donors of human cellular and tissue-based products (64 FR 52696, September 30, 1999), which is intended to replace part 1270 when finalized.

TABLE 1. — ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1270.31(a) and 1270.31(b)[2]	56	1	56	24.0	1,344
1270.31(a) and 1270.31(b)[3]	56	2	102	1.0	102
1270.33(a), (f), and (h), and 1270.35(a) and (b)	56	195.57	10,952	1.0	10,952
127.35(c)	56	6,222.79	348,476	1.0	348,476
1270.35(d)	56	384.18	21,514	1.0	21,514
Total					382, 388

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Review and update of SOP's.
[3]Documentation of deviations from SOP's.

Dated: December 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–263 Filed 1–4–01; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1494]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Classification/ Reclassification; Restricted Devices: Analyte Specific Reagents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by February 5, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices: Classification/ Reclassification; Restricted Devices; Specific Reagents—21 CFR Part 809 (OMB Control No. 0910–0361)— Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352) establishes certain labeling requirements for devices including requirements that the labeling not be false or misleading in any particular, that the labeling contain the established name for the device, and that the labeling contain adequate directions for use. Section 520(e) of the act (21 U.S.C. 360j(e)) provides that FDA may restrict the sale, distribution, or use of a device, if FDA determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. Section 502(q) and (r) of the act authorizes FDA to regulate the advertising of devices that are restricted under section 520(e) of the act.

FDA restricts distribution of analyte specific reagents (ASR's) to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity testing, to manufacturers of in vitro diagnostic products, and to organizations that use the tests for reasons other than providing diagnostic information to practitioners and patients. FDA has established certain labeling requirements for suppliers of ASR's and certain requirements regarding advertising and promotional materials for ASR's. FDA believes the labeling requirements and restrictions on advertising and promotion are necessary to ensure that laboratories developing tests from ASR's have sufficient information to use the ASR's appropriately and to limit specific claims by manufacturers, because these ASR's are intended to be used as ingredients in a variety of ways by laboratories qualified to do high complexity testing.

The most likely respondents to this information collection will primarily be medical device manufacturers of in vitro products, clinical laboratories, and other manufacturers of ASR's.

In the **Federal Register** of September 14, 2000 (65 FR 55633), the agency requested comments on the proposed collection of information. One comment, discussing three separate issues, was received.

1. The comment first asked that medical device manufacturers provide basic laboratory instructions for use and warn against uses that are not appropriate for the particular ASR.

FDA was not persuaded by this comment. The intention of the ASR rule is to ensure that laboratories using these products to develop in-house or ''home brew'' tests take full responsibility for the development of the ''home brew'' test and for the characterization of test performance for the ASR based test. ASR use is restricted to high-complexity laboratories under the CLIA which have the ability to develop tests based on their own experience or the medical literature. The instructions for use in different laboratories using ASR's would be expected to vary with the experience of the laboratory and with the information obtained during test development and characterization.

If a medical device manufacturer wishes to provide laboratory instructions on product use, this is acceptable. However, this is evidence that a kit or system is being marketed rather than used as an ASR or building block for an assay. Such a device would not be exempt from premarket review by FDA.

2. The comment further indicated that a guidance or written clarification as to the scope of appropriate warnings and precautions would be helpful.

FDA does not believe such guidance or written clarification is necessary. The regulation in 21 CFR 809.10(e)(1)(v) requires ''A statement of warnings or precautions for users as established in the regulations contained in 16 CFR part

1500 and any other warnings appropriate to the hazard presented by the product.'' Hazards in use of laboratory reagents are well known and the subject of multiple book chapters and a voluntary standard. The information required which includes, as appropriate, warnings regarding flammability, toxicity, teratogenicity, and carcinogenicity are well known by both manufacturers and laboratory users. Additional information on these would duplicate existing commonly used information sources and conditions of art.

3. Finally, the comment indicated that product support dictates that information be provided to users on proper set up of instruments, preparation of samples, and the generation of good quality data.

FDA agrees that the information cited is of key importance in test performance. For ''home brew'' tests, however, the responsibility for developing this information is clearly assigned to the laboratory, not to the manufacturer of the ASR. The only responsibility the ASR manufacturer has is to produce product according to the quality system regulations, to label it clearly as a building block for use in ''home brew'' assays, and to restrict sales to high complexity laboratories. These laboratories by law have the personnel standards, proficiency testing, quality control and quality assurance requirements, and requirements for controlled operating environments needed in the development of quality ''home brew'' tests.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
809.10(e)	300	25	7,500	1	7,500
809.30(d)	300	25	7,500	1	7,500
Total					15,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of affected establishments was derived by asking five organizations for estimates and averaging their responses to arrive at an average number of establishments affected by this rule. These organizations included the largest trade association representing the in vitro diagnostic industry, the larger trade association for nonbiotechnology products, two of the largest organizations representing laboratory professionals, and the in vitro diagnostic company instrumental in providing industry input into the implementation of this rule. Three of the five organizations had access to data bases allowing them to project estimates of establishments likely to manufacture or supply ASR's. These estimates ranged from 100 to 500. FDA therefore used the average of 300 ASR manufacturers and suppliers subject to the reporting requirements from these estimates.

FDA relied upon the five trade organizations in estimating the number of ASR's manufactured. Again, three of the organizations offered information from their data bases. Estimates for the number of ASR's ranged from 5,000 to 10,000, with the average being 7,500. FDA therefore estimates that approximately 7,500 ASR's are currently being manufactured.

In order to ascertain the number of ASR's manufactured by each respondent, FDA used the average number of ASR's manufactured and divided it by the number of ASR manufacturers (7,500 ÷ 300). Consequently, the estimate of the number of ASR's manufactured by each respondent is approximately 25. (In the previously published final rule of November 21, 1997 (62 FR 62243), the total number of ASR's were listed as ''1,'' and the number of respondent burden hours associated with ASR's were ''25.'' These numbers were reversed in error.)

FDA estimates that for each ASR, it would take approximately 1 hour to design a new label to conform with the new requirements and approximately 3 hours to provide management review and legal and marketing sign-off. Therefore, FDA estimates that the total number of hours needed to design/review labels is approximately 100 hours per respondent (25 x 4). The total number of hours to design/review labels by all establishments is estimated at 30,000 (100 x 300). However, these estimates do not take into account economies of scale in designing and revising the labeling on ASR's, which should reduce the time expended in ASR labeling by 75 percent. Consequently, FDA estimates that the total number of reporting hour burden for designing/review of labeling is approximately 25 hours per respondent instead of 100. FDA also estimates that the total reporting hour burden is approximately 7,500 hours instead of 30,000.

FDA estimates for each ASR, it would take approximately 1 hour to rewrite the professional materials to ascertain compliance with the new requirements and approximately 4 hours to obtain management review of rewritten materials and legal and marketing sign-off. FDA therefore estimates that the total number of hours to rewrite/review promotional materials is approximately 125 hours per respondent (25 ASR's per respondent x 5 hours for review). The total reporting hours for all ASR's is estimated at 37,500 (125 hours x 300 manufacturer/suppliers). However, this estimate does not take into account economies of scale. Often the promotional materials are a catalogue of products. FDA estimates that entities spend approximately 20 percent of the time devoted to reporting ASR's (37,500 hours) ascertaining that the promotional materials meet the new requirements. Consequently, FDA estimates that the total number of reporting hour burden for rewriting/reviewing promotional materials under 21 CFR 809.30(d) is approximately 25 hours per respondent (125 x .20), and estimates that the total reporting hour burden for promotional materials is approximately 7,500 hours (37,500 x .20).

Dated: December 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–260 Filed 1–4–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1511]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Petition for Administrative Reconsideration of Action

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by February 5, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Petition for Administrative Reconsideration of Action—21 CFR 10.33 (OMB Control Number 0910–0192)—Extension

The regulations in 21 CFR 10.33, issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)), set forth the format and procedures by which an interested person may petition the Commissioner of Food and Drugs (the Commissioner) for reconsideration of an agency action. A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or adequately considered by the Commissioner. Each petition must be submitted no later than 30 days after the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions.

In the **Federal Register** of September 25, 2000 (65 FR 57615), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.33(b)	12	1	12	10	120

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this collection of information is based on agency records and experience over the past 3 years. Agency personnel handling the petitions for administrative reconsideration of an action estimate approximately 12 requests being received by the agency annually, each requiring an average of 10 hours preparation time.

Dated: December 27, 2000.

Margaret M. Dotzel,

Associate Commisioner for Policy.

[FR Doc. 01–261 Filed 1–4–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1674]

Agency Information Collection Activities; Proposed Collection; Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of ''Geriatric Use'' Subsection in the Labeling; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the ''Geriatric Use'' subsection in the labeling for human prescription drugs.

DATES: Submit written comments or electronic comments on the collection of information by March 6, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600

Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of ''Geriatric Use'' Subsection in the Labeling (OMB Control Number 0910–0370)—Extension

Section 201.57(f)(10) (21 CFR 201.57(f)(10)) requires that the ''Precautions'' section of prescription drug labeling must include a subsection on the use of the drug in elderly or geriatric patients (aged 65 and over). The information collection burden imposed by this regulation consists of designing, testing, and submitting the geriatric use subsection of the labeling. The regulation is necessary to facilitate the safe and effective use of prescription drugs in older populations. The geriatric use subsection enables physicians to more effectively access geriatric information in physician prescription drug labeling.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10)—new drug applications	83	1.49	124	8	992
201.57(f)(10)—abbreviated new drug applications	117	3.96	464	2	928
Total					1,920

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–264 Filed 1–4–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1534]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Year 2000 Continuation of the National Surveys of Prescription Drug Information Provided to Patients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by February 5, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Year 2000 Continuation of the National Surveys of Prescription Drug Information Provided to Patients

FDA implements the provisions of the Federal Food, Drug, and Cosmetic Act (the act) designed to assure the adequate labeling of prescription (Rx) drugs. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug product is misbranded if its labeling is false or misleading in any particular, and under section 201(n) of the act (21 U.S.C. 321(n)), a drug's labeling is misleading if its labeling or advertising fails to reveal material facts. FDA also has the authority to collect this information under Title VI of Public Law 104–180 (Related Agencies and Food and Drug Administration) section 601 (Effective Medication Guides), which directs the development of ''a mechanism to assess periodically * * * the frequency with which the [oral and written prescription] information is provided to consumers.''

To assure that Rx drugs are not misbranded, FDA has historically asserted that adequate labeling requires certain information be provided to patients. In 1982, when FDA revoked a planned initiative to require mandatory patient package inserts for all Rx drugs in favor of private sector initiatives, the agency indicated that it will periodically conduct surveys to evaluate the availability of adequate patient information on a nationwide basis. In addition, FDA has been responsible for setting and tracking Healthy People 2000 goals and now for Healthy People 2010 goals for the receipt of medication information by patients.

Surveys of consumers about their receipt of Rx drug information were carried out in 1982, 1984, 1992, 1994, 1996, and 1998. This notice is in regard to conducting the survey in 2000.

The survey is conducted by telephone on a national random sample of adults who received a new prescription for themselves or a household member within the past 4 weeks. The interview assesses the extent to which oral and written information were received from the doctor, the pharmacist, and other sources. Survey respondents are also asked attitudinal questions, and demographic and other background characteristics are obtained. The survey enables FDA to determine the frequency with which such information is provided to consumers. Without this information, the agency would be unable to assess the degree to which adequate patient information and counseling about Rx drugs is provided.

Respondents to this collection of information are adults (18 years or older) in the continental United States who have obtained a new (nonrefill) prescription at a pharmacy for themselves or a member of their household in the last 4 weeks. This survey may be seen online at http://www.fda.gov/cder/ddmac/y2ktitle.htm.

In the **Federal Register** of October 6, 2000 (65 FR 59849), FDA invited comments on the proposed information collection. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]: SCREENER

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2000	9,643	1	9,643	.03	289
Total					289

[1]There are no capital costs or operating and maintenance costs associated with this collection of information

TABLE 2.—ANNUAL REPORTING BURDEN[1]: SURVEY

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2000	1,000	1	1,000	.32	320
Total					320

[1]There are no capital costs or operating and maintenance costs associated with this collection of information

This total estimate of 609 total annual burden hours is based on the 1998 survey administration, in which 9,643 potential respondents were contacted to obtain 1,000 interviews.

Dated: December 27, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–265 Filed 1–4–01; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0472]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Petition for Administrative Stay of Action

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by February 5, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Petition for Administrative Stay of Action—21 CFR 10.35 (OMB Control Number 0910–0194)—Reinstatement)—Extension

The regulations in 21 CFR 10.35, issued under the authority of section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)), set forth the format and procedures by which an interested person may file a petition for an administrative stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action. Such a petition must: (1) Identify the decision involved; (2) state the action requested, including the length of time for which a stay is requested; and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. The information provided in the petition is used by the agency to determine whether the requested stay should be granted.

In the **Federal Register** of September 25, 2000 (65 FR 57614), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1. — ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.35	13	1	13	10	130

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this collection of information is based on FDA's experience with petitions for administrative stay of action over the past 3 years. Agency personnel responsible for processing the filing of petitions for administrative stays of action estimate that 13 such petitions are received by the agency annually, with each requiring approximately 10 hours of preparation time.

Dated: December 27, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–266 Filed 1–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 19, 2001, 9:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact: Hany W. Demian, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a cervical interbody fusion system.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 12, 2001. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m., and an additional 30 minutes of open public hearing will be scheduled prior to the end of committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 12, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 28, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–267 Filed 1–4–01; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the President's Cancer Panel.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: President's Cancer Panel.

Date: February 1–2, 2001.

Time: 9 am to 4 pm.

Agenda: Improving Cancer Care for All: Real People—Real Problems.

Place: USC/Norris Comprehensive Cancer Center, University of Southern California, 1441 Eastlake Avenue, Los Angeles, CA 90033.

Contact Person: Maureen O. Wilson, Executive Secretary, National Cancer Institute, National Institutes of Health, 31 Center Drive, Building 31, Room 4A48, Bethesda, MD 20892, 301/496–1148.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 27, 2000.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–334 Filed 1–4–01; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel.

Date: January 4, 2001.

Time: 9 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: 6120 Executive Blvd. Suite 350, Rockville, MD 20892.

Contact Person: Andrew P Mariani, PhD, Chief, Scientific Review Branch, 6120 Executive Blvd, Suite 350, Rockville, MD 20892, 301/496–5561.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: December 22, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–336 Filed 1–4–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology and Infectious Diseases Research Committee.

Date: February 7–9, 2001.

Open: February 7, 2001, 9 a.m. to 10 a.m..

Agenda: Reports from various Institute staff.

Place: Holiday Inn Georgetown, Mirage II, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Closed: February 7, 2001, 10 a.m. to adjournment on February 9, 2001.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, Mirage II, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Gary S. Madonna, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2217, 6700–B Rockledge Drive, MSC 7610, Bethesda, MD 20892–7610, 301–496–2550.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 22, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–335 Filed 1–4–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6). Title 5 U.S.C., as amended. The journals as potential titles to be indexed by the National Library of Medicine and the discussions could disclose confidential trade secrets of commercial property such as patentable material, and personal information concerning individuals associated with the journals as potential titles to be indexed by the National Library of Medicine, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Literature Selection Technical Review Committee.

Date: February 8–9, 2001.

Open: February 8, 2001, 9am to 11am.

Agenda: Administrative Reports and Program Developments.

Place: National Library of Medicine, Board Room Bldg 38, 2E–09, 8600 Rockville Pike, Bethesda, MD 20894.

Closed: February 8, 2001, 11 am to 5 pm.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

*Place:*National Library of Medicine, Board Room Bldg 38, 2E–09, 8600 Rockville Pike, Bethesda, MD 20894.

Closed: February 9, 2001, 8:30 am to 2 pm.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: National Library of Medicine, Board Room Bldg 38, 2E–09, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Sheldon Kotzin, BA, Chief, Bibliographic Services Division, Division of Library Operations, National Library of Medicine, 8600 Rockville Pike, Bldg 38A/Room 4N419, Bethesda, MD 20894.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: December 27, 2000.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–333 Filed 1–4–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Action Under the Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: This notice amends the NIH Guidelines to set forth NIH's policy on in utero gene transfer clinical research. At the present time, there is insufficient basic and preclinical data to justify the conduct of in utero gene transfer clinical research. Before any in utero gene transfer clinical trial could proceed, significant additional preclinical and relevant clinical studies addressing biodistribution, toxicity, and efficiency of vector transduction would be required, as would further deliberations of the ethical issues associated with this research. As new knowledge evolves from basic, preclinical, and relevant clinical research and as the ethical issues are addressed, the NIH would consider in utero gene transfer clinical protocols for review by the Recombinant DNA Advisory Committee (RAC).

FOR FURTHER INFORMATION CONTACT: Background documentation and additional information can be obtained from the Office of Biotechnology Activities (OBA), National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, Phone 301–496–9838, FAX 301–496–9839. The OBA Web site is located at http://www.nih.gov/od/oba/.

Background Information

In September 1998, the NIH RAC discussed two preliminary proposals for human in utero gene transfer and

recommended a comprehensive public review of the scientific and ethical issues raised by such studies. In response, NIH convened a national Gene Therapy Policy Conference on Prenatal Gene Transfer: Scientific, Medical, and Ethical Issues (January 7–8, 1999) to further explore these issues.

The findings and conclusions of the Conference indicated that, at present, there is insufficient preclinical data to support the initiation of clinical trials involving in utero gene transfer clinical research. A substantial number of critical scientific, safety, ethical, legal, and social issues must be addressed before clinical trials proceed in this arena including: (1) Efficiency of gene transfer to target cells; (2) specificity of delivery to target cells; (3) level, duration, and regulation of gene expression; (4) appropriate disease candidates; (5) fetal immune response to transgene products and/or vectors; (6) emergence of fetal immune tolerance; (7) effects of gene transfer on pre- and post-natal development; (8) possibility of generation and activation of transmissible vector or virus; (9) possibility of initiating oncogenic or degenerative processes; (10) limitations related to the accuracy of disease diagnosis; (11) implications of diagnostic limitations on the design and conduct of clinical trials; (12) elements of optimal clinical trial design and analysis; (13) potential risk to the fetus and acceptable level of risk to the fetus in human experimentation; (14) potential risk to the pregnant woman; (15) detection and assessment of inadvertent germ-line transmission; (16) ethical issues specific to the fetus; (17) ethical issues specific to the pregnant woman; (18) patient recruitment/enrollment processes; (19) informed consent issues; (20) societal issues; and (21) legal issues. (See http://www4.od.nih.gov/oba/gtpcreport.pdf for further information.)

In March 1999, RAC discussed the findings and conclusions of the conference and developed the following consensus statement: ''The RAC continues to explore the issues raised by the potential of in utero gene transfer research. However, at present, the members unanimously agree that it is premature to undertake any human in utero gene transfer experiment.'' After providing an opportunity for public comments (64 FR 43884), the RAC unanimously recommended that this consensus statement be adopted as policy and incorporated into the NIH Guidelines (Appendix M). The NIH is implementing this recommendation through this notice of action.

Action Amending the NIH Guidelines

Appendix M. Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules into One or More Human Research Participants (Points to Consider)

Appendix M is amended by adding the following paragraph after the third paragraph:

''The RAC continues to explore the issues raised by the potential of in utero gene transfer clinical research. However, the RAC concludes that, at present, it is premature to undertake any in utero gene transfer clinical trial. Significant additional preclinical and clinical studies addressing vector transduction efficacy, biodistribution, and toxicity are required before a human in utero gene transfer protocol can proceed. In addition, a more thorough understanding of the development of human organ systems, such as the immune and nervous systems, is needed to better define the potential efficacy and risks of human in utero gene transfer. Prerequisites for considering any specific human in utero gene transfer procedure include an understanding of the pathophysiology of the candidate disease and a demonstrable advantage to the in utero approach. Once the above criteria are met, the RAC would be willing to consider well rationalized human in utero gene transfer clinical trials.''

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally, NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which recombinant DNA techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: December 28, 2000.

Ruth L. Kirschstein,

Acting Director, National Institutes of Health.

[FR Doc. 01–337 Filed 1–4–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Pilot Testing of Outcome Measures in Programs Providing Services to Persons Who are Homeless and Have Serious Mental Illnesses—New—SAMHSA's Center for Mental Health Services (CMHS) provides funds to states and territories to provide services to individuals who are homeless and have serious mental illnesses. These services enable persons who are homeless and have serious mental illnesses to be placed in appropriate housing situations and linked to mental health services. To comply with requests for client outcome data, State and local providers have sought measures which could help them more effectively monitor and manage their programs as well as demonstrate program effectiveness.

Interest in performance measurement and evaluation of policies, programs and individual services has increased

dramatically with the passage of the Government Performance and Results Act (GPRA) in 1993. GPRA focuses new attention on the quality of outcome measures used to collect information about publicly funded programs. Programs that provide services to persons who are homeless and have serious mental illnesses are facing greater need to document their effectiveness. These outcome data will ultimately be used in responding to Congressional and HHS oversight, GPRA requirements, and the requests of other governmental levels, managed care companies, and private funding sources.

The project will test the appropriateness and feasibility of selected indicators to measure the outcome of services to persons who are homeless and have serious mental illnesses. Outcome measures to be evaluated include housing status, sobriety or drug-free status, mental health treatment status, enrollment in an educational program, and employment.

In addition, the project will evaluate process measures pertaining to outreach, service delivery and linkage stages of intervention. These process indicators include the type of contact (*i.e.*, referrals, walk-ins, fixed outreach, and mobile outreach); whether the person contacted agreed to services, reasons for any non-enrollment, and referral to, and provision of, specific services.

The project will test these outcome and process measures in a total of approximately six provider agencies in each of five participating States. The findings of the pilot test will serve as the basis for recommendations for a voluntary national implementation of data collection in similar programs, nationwide. It will also test the feasibility of compiling such data in a central data collection point.

Local providers will report information on services provided to individuals served. Providers will report aggregate information from their records for all new clients during a one-month period. Information will be reported on the initial client contact, on services clients receive over the next six months and on client outcomes at the end of six months. In addition, half of the provider agencies will report client followup information at a period 60 days after the conclusion of the six-month period. It is anticipated that this information will be collated from existing provider records. Data will be submitted to the central data point in aggregate form, not by individual client. Projected response burden for the project is summarized in the table below.

	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Initial and six-month aggregate report	30	1	10	300
Follow-up aggregate report	15	1	10	150
Total	30	.....	.....	450

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 29, 2000.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 01–309 Filed 1–4–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This Notice is also available on the internet at the following website: *http://www.health.org/workplace*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443–6014, Fax: (301) 443–3031.

Special Note: Please use the above address for all surface mail and correspondence. For all overnight mail service use the following address: Division of Workplace Programs, 5515 Security Lane, Room 815, Rockville, Maryland 20852.

SUPPLEMENTARY INFORMATION: Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories

meet the minimum standards set forth in the Guidelines:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016 (Formerly: Bayshore Clinical Laboratory)

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800–541–4931 / 334–263–5745

Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513–585–9000 (Formerly: Jewish Hospital of Cincinnati, Inc.)

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 20151, 703–802–6900

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866/800–433–2750

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Laboratory Partners, LLC, 129 East Cedar St., Newington, CT 06111, 860–696–8115 (Formerly: Hartford Hospital Toxicology Laboratory)

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652/417–269–3093 (Formerly: Cox Medical Centers)

Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, Building 38-H, P. O. Box 88–6819, Great Lakes, IL 60088–6819, 847–688–2045/847–688–4171

Diagnostic Services Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 941–561–8200/800–735–5416

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31602, 912–244–4468

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206–386–2672 / 800–898–0180, (Formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215–674–9310

Dynacare Kasper Medical Laboratories *, 14940–123 Ave., Edmonton, Alberta, Canada T5V 1B4, 780–451–3702/800–661–9876

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 662–236–2609

Express Analytical Labs, 1301 18th Ave NW, Suite 110, Austin, MN 55912, 507–437–7322

Gamma-Dynacare Medical Laboratories *, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall St., London, ONT, Canada N6A 1P4, 519–679–1630

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6267

Integrated Regional Laboratories, 5361 NW 33rd Avenue, Fort Lauderdale, FL 33309, 954–777–0018, 800–522–0232 (Formerly: Cedars Medical Center, Department of Pathology)

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823 (Formerly: Laboratory Specialists, Inc.)

LabOne, Inc., 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–728–4064 (Formerly: Center for Laboratory Services, a Division of LabOne, Inc.)

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem, Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 4022 Willow Lake Blvd., Memphis, TN 38118, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc., MedExpress/National Laboratory Center)

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.)

Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715–389–3734/800–331–3734

MAXXAM Analytics Inc.*, 5540 McAdam Rd., Mississauga, ON, Canada L4Z 1P1, 905–890–2555 (Formerly: NOVAMANN (Ontario) Inc.)

Medical College Hospitals Toxicology Laboratory, Department of Pathology, 3000 Arlington Ave., Toledo, OH 43699, 419–383–5213

MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 651–636–7466/800–832–3244

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, Minnesota 55417, 612–725–2088

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515

Northwest Drug Testing, a division of NWT Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 801–293–2300/800–322–3361 (Formerly: NWT Drug Testing, NorthWest Toxicology, Inc.)

One Source Toxicology Laboratory, Inc., 1705 Center Street, Deer Park, TX 77536, 713–920–2559 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)

Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440–0972, 541–687–2134

Pacific Toxicology Laboratories, 6160 Variel Ave., Woodland Hills, CA 91367, 818–598–3110/800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory

Pathology Associates Medical Laboratories, 11604 E. Indiana Ave., Spokane, WA 99206, 509–926–2400/800–541–7891

PharmChem Laboratories, Inc., 1505–A O'Brien Dr., Menlo Park, CA 94025, 650–328–6200/800–446–5177

PharmChem Laboratories, Inc., Texas Division, 7606 Pebble Dr., Fort Worth, TX 76118, 817–215–8800 (Formerly: Harris Medical Laboratory)

Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913–339–0372/800–821–3627

Poisonlab, Inc., 7272 Clairemont Mesa Blvd., San Diego, CA 92111, 858–279–2600 / 800–882–7272

Quest Diagnostics Incorporated, 3175 Presidential Dr., Atlanta, GA 30340, 770–452–1590 (Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 4444 Giddings Road, Auburn Hills, MI 48326, 248–373–9120 / 800–444–0106 (Formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath, CORNING Clinical Laboratories)

Quest Diagnostics Incorporated, 8000 Sovereign Row, Dallas, TX 75247 214–638–1301 (Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 4770 Regent Blvd., Irving, TX 75063, 972–916–3376/800–526–0947 (Formerly: Damon Clinical Laboratories, Damon/MetPath, CORNING Clinical Laboratories)

Quest Diagnostics Incorporated, 801 East Dixie Ave., Suite 105A, Leesburg, FL 34748, 352–787–9006x4343 (Formerly: SmithKline Beecham Clinical Laboratories, Doctors & Physicians Laboratory)

Quest Diagnostics Incorporated, 400 Egypt Rd., Norristown, PA 19403, 610–631–4600/800–877–7484 (Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 506 E. State Pkwy., Schaumburg, IL 60173, 800–669–6995/847–885–2010 (Formerly: SmithKline Beecham Clinical Laboratories, International Toxicology Laboratories)

Quest Diagnostics Incorporated, 7470 Mission Valley Rd., San Diego, CA 92108–4406, 619–686–3200/800–446–4728 (Formerly: Nichols Institute, Nichols Institute Substance Abuse Testing (NISAT), CORNING Nichols Institute, CORNING Clinical Laboratories)

Quest Diagnostics Incorporated, One Malcolm Ave., Teterboro, NJ 07608, 201–393–5590 (Formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories, CORNING Clinical Laboratory)

Quest Diagnostics Incorporated, 7600 Tyrone Ave., Van Nuys, CA 91405, 818–989–2520/800–877–2520 (Formerly: SmithKline Beecham Clinical Laboratories)

San Diego Reference Laboratory, 6122 Nancy Ridge Dr., San Diego, CA 92121, 800–677–7995/858–677–7970
Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804–378–9130
Scott & White Drug Testing Laboratory, 600 S. 25th St., Temple, TX 76504, 254–771–8379/800–749–3788
S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505–727–6300/800–999–5227
South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 219–234–4176
Southwest Laboratories, 2727 W. Baseline Rd., Tempe, AZ 85283, 602–438–8507/800–279–0027
Sparrow Health System, Toxicology Testing Center, St. Lawrence Campus 1210 W. Saginaw, Lansing, MI 48915 517–377–0520 (Formerly: St. Lawrence Hospital & Healthcare System)
St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405–272–7052
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 2703 Clark Lane, Suite B, Lower Level, Columbia, MO 65202, 573–882–1273
Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305–593–2260,
UNILAB 18408 Oxnard St., Tarzana, CA 91356, 818–996–7300/800–339–4299 (Formerly: MetWest-BPL Toxicology Laboratory)
Universal Toxicology Laboratories, LLC 9930 W. Highway 80, Midland, TX 79706, 915–561–8851/888–953–8851

The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. DHHS, with the DHHS' National Laboratory Certification Program (NLCP) contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, the DHHS will recommend that DOT certify the laboratory (**Federal Register**, 16 July 1996) as meeting the minimum standards of the ''Mandatory Guidelines for Workplace Drug Testing'' (59 **Federal Register**, 9 June 1994, Pages 29908–29931). After receiving the DOT certification, the laboratory will be included in the monthly list of DHHS certified laboratories and participate in the NLCP certification maintenance program.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 01–64 Filed 1–4–01; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered Species Permit Applications

AGENCY: Fish and Wildlife Service, DOI.

ACTION: Notice of receipt of permit applications.

SUMMARY: The following applicants have applied for a scientific research permit to conduct certain activities with endangered species pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Permit No. TE–036120

Applicant: Michael Stephen Powers, San Diego, California

The applicant requests a permit to take (survey by pursuit) the Quino checkerspot butterfly (*Euphydryas editha quino*) in conjunction with presence or absence surveys throughout its range for the purpose of enhancing its survival.

Permit No. TE–036065

Applicant: Korey Klutz, Chula Vista, California

The applicant requests a permit to take (survey by pursuit) the Quino checkerspot butterfly (*Euphydryas editha quino*) in conjunction with presence or absence surveys throughout its range for the purpose of enhancing its survival.

Permit No. TE–027736

Applicant: David Erik LaCoste, Ramona, California

The permittee requests a permit amendment to take (survey by pursuit) the Quino checkerspot butterfly (*Euphydryas editha quino*) in conjunction with presence or absence surveys throughout its range for the purpose of enhancing its survival.

Permit No. TE–036034

Applicant: Tierra Data Systems, Escondido, California

The applicant requests a permit to remove and reduce to possession specimens of *Arctostaphylos glandulosa* ssp. *crassifolia* (Del Mar manzanita), *Chorizanthe orcuttiana* (Orcutt's spineflower), and *Fremontodendron mexicanum* (Mexican flannelbush) in conjunction with collecting voucher specimens throughout each species' range for the purpose of enhancing their survival.

Permit No. TE–807078

Applicant: Point Reyes Bird Observatory, Stinson Beach, California

The permittee requests an amendment to extend the geographic area and take (harass, capture and band) the California least tern (*Sterna antilluarum browni*) in conjunction with monitoring throughout the Oakland-San Francisco Bay area in California for the purpose of enhancing its survival.

This application for the California least tern was published in the **Federal Register** on June 20, 2000, for Alameda County, California.

Permit No. TE–035879

Applicant: Wildlands, Inc., Citrus Heights, California

The applicant requests a permit to take (harass by survey, collect and sacrifice) the Conservancy fairy shrimp (*Branchinecta conservatio*), longhorn fairy shrimp (*Branchinecta longiantenna*), vernal pool tadpole shrimp (*Lepidurus packardi*), San Diego fairy shrimp (*Brachinecta sandiegonensis*), and the Riverside fairy shrimp (*Streptocephalus woottoni*) in conjunction with surveys and identification of conservation areas, throughout each species' range in California for the purpose of enhancing their survival.

Permit No. TE–021544

Applicant: Salavatore Zimmitti, San Diego, California

The applicant requests a permit to take (harass by survey, collect and sacrifice) the Conservancy fairy shrimp (*Branchinecta conservatio*), longhorn fairy shrimp (*Branchinecta longiantenna*), vernal pool tadpole shrimp (*Lepidurus packardi*), San Diego fairy shrimp (*Brachinecta sandiegonensis*), and the Riverside fairy shrimp (*Streptocephalus woottoni*) in conjunction with surveys and identification of conservation areas, throughout each species' range in California for the purpose of enhancing their survival.

Permit No. TE–035514

Applicant: Kevin J. Roe, University of Alabama, Tuscaloosa, Alabama

The applicant requests a permit to take (collect and sacrifice) the California

freshwater shrimp (*Syncaris pacifica*) in conjunction with genetics research throughout the species range in California for the purpose of enhancing its survival.

Permit No. TE–036138

Applicant: Wendy Hooper, Ahwahnee, California

The applicant requests a permit to take (harass by survey, collect and sacrifice) the Conservancy fairy shrimp (*Branchinecta conservatio*), longhorn fairy shrimp (*Branchinecta longiantenna*), vernal pool tadpole shrimp (*Lepidurus packardi*), San Diego fairy shrimp (*Brachinecta sandiegonensis*), and the Riverside fairy shrimp (*Streptocephalus woottoni*) in conjunction with surveys throughout each species' range in California for the purpose of enhancing their survival.

Permit No. TE–768251

Applicant: Biosearch Wildlife Surveys, Santa Cruz, California

The permittee requests an amendment to take (capture and handle; collect tissue samples) the California tiger salamander (*Ambystoma californiense*) in conjunction with presence or absence surveys and genetic research in Santa Barbara County, California for the purpose of enhancing its survival.

Permit No. TE–797234

Applicant: LSA Associates, Inc., Point Richmond, California

The permittee requests an amendment to take (capture and handle; collect tissue samples) the California tiger salamander (*Ambystoma californiense*) in conjunction with presence or absence surveys and genetic research in Santa Barbara County, California for the purpose of enhancing its survival.

Permit No. TE–836521

Applicant: Dan Holland, Fallbrook, California

The permittee requests an amendment to take (capture) the San Francisco garter snake (*Thamnophis sirtalis tetrataenia*) in conjunction with surveys through out the species' range in California for the purpose of enhancing its survival.

Permit No. TE–025582

Applicant: URS, San Diego, California

The applicant requests a permit to: take (harass by survey) California clapper rail (*Rallus longirostris obsoletus*), light-footed clapper rail (*Rallus longirostris levipes*), and Yuma clapper rail (*Rallus longirostris yumanensis*); take (harass by survey and monitor nests) the coastal California gnatcatcher (*Polioptila californica californica*) and southwestern willow flycatcher (*Empidonax traillii extimus*); take (capture, handle, and release) the San Francisco garter snake (*Thamnophis sirtalis tetrataenia*), riparian brush rabbit (*Sylvilagus bachmani riparius*), blunt-nosed leopard lizard (*Gambelia silus*), southwestern arroyo toad (*Bufo microscaphus californicus*), Fresno kangaroo rat (*Dipodomys nitratoides exilis*), giant kangaroo rat (*Dipodomys ingens*), Tipton kangaroo rat (*Dipodomys nitratoides nitratoides*), Pacific pocket mouse (*Pergnathus longimembris pacificus*), Stephens' kangaroo rat (*Dipodomys stephensi*), San Bernardino merriam's kangaroo rat (*Dipodomys merriami parvus*), salt marsh harvest mouse (*Reithrodontomys raviventris*), Mohave tui chub (*Gila bicolor mohavensis*), Owens tui chub (*Gila bicolor snyderi*), Lost river sucker (*Deltistes luxatus*), razorback sucker (*Xyraunchen texanus*), desert pupfish (*Cyprinodon radiosus*), unarmored threespine stickleback (*Gasterosteus aculeatus williamsoni*), desert slender salamander (*Batrachoseps aridus*), and tidewter goby (*Eucyclogobius newberryi*); take (capture and handle; collect tissue samples) the California tiger salamander (*Ambystoma californiense*); take (survey by pursuit) the Quino checkerspot butterfly (*Euphydryas editha quino*), El Segundo blue butterfly (*Euphilotes battoides allyni*), and Delhi sand's flower-loving fly (*Rhaphiomidas terminatus abdominalis*); take (harass by survey, collect, and sacrifice) the Conservancy fairy shrimp (*Branchinecta conservatio*), longhorn fairy shrimp (*Branchinecta longiantenna*), vernal pool tadpole shrimp (*Lepidurus packardi*), California freshwater shrimp (*Syncaris pacifica*), San Diego fairy shrimp (*Brachinecta sandiegonensis*), and the Riverside fairy shrimp (*Streptocephalus woottoni*) in conjunction with surveys throughout each species' range for the purpose of enhancing their survival.

Permit No. TE–036890

Applicant: Virginia Moran, Julian, California

The applicant requests a permit to take (survey by pursuit) the Quino checkerspot butterfly (*Euphydryas editha quino*) in conjunction with presence or absence surveys throughout its range for the purpose of enhancing its survival.

Permit No. TE–036550

Applicant: Nina Jimerson, Aliso Viejo, California

The applicant requests a permit to take (survey by pursuit) the Quino checkerspot butterfly (*Euphydryas editha quino*) in conjunction with presence or absence surveys throughout its range for the purpose of enhancing its survival.

Permit No. TE–036922

Applicant: Rebecca Loomis, San Diego, California

The applicant requests a permit to take (survey by pursuit) the Quino checkerspot butterfly (*Euphydryas editha quino*) in conjunction with presence or absence surveys throughout its range for the purpose of enhancing its survival.

Permit No. TE–787376

Applicant: Peter Bloom, Santa Ana, California

The permittee requests an amendment to take (harass by survey, locate and monitor nests, capture, mark, band, and release) the southwestern willow flycatcher (*Empidonax traillii extimus*) in conjunction with surveys and scientific research throughout its species range in California for the purpose of enhancing its survival.

DATES: Written comments on these permit applications must be received on or before February 5, 2001.

ADDRESSES: Written data or comments should be submitted to the Chief-Endangered Species, Ecological Services, Fish and Wildlife Service, 911 NE. 11th Avenue, Portland, Oregon 97232–4181; Fax: (503) 231–6243. Please refer to the respective permit number for each application when submitting comments. All comments received, including names and addresses, will become part of the official administrative record and may be made available to the public.

FOR FURTHER INFORMATION CONTACT: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 20 days of the date of publication of this notice to the address above; telephone: (503) 231–2063. Please refer to the respective permit number for each application when requesting copies of documents.

Dated: December 28, 2000.

Daniel H. Diggs,

Regional Director, Region 1, Portland, Oregon.

[FR Doc. 01–310 Filed 1–4–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM091–9941–EK–HE931]

Extension of Approved Information Collection, OMB Approval Number 1004–0180

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) announces its intention to request extension of an existing approval to collect certain information from owners and operators of helium-bearing natural gas wells and transmission lines pertaining to natural gas analyses. BLM uses this information to evaluate the helium resources of the United States (BLM Form 3100–12).

DATES: You must submit your comments to BLM at the appropriate address below on or before March 6, 2001. BLM will not necessarily consider any comments received after the above date.

ADDRESSES: Comments may be mailed to: Regulatory Affairs Group (630), Bureau of Land Management, 1849 C Street NW, Room 401LS, Washington, DC 20240.

Comments may be sent via Internet to: *WOComment@blm.gov*. Please include ''ATTN: 1004–0180'' and your name and return address in your Internet message.

Comments may be hand-delivered to the Bureau of Land Management, Administrative Record, Room 401, 1620 L Street, NW, Washington, DC.

Comments will be available for public review at the L Street address during regular business hours (7:45 a.m. to 4:15 p.m.), Monday through Friday.

FOR FURTHER INFORMATION CONTACT: You may contact Brent Gage on (806) 324–2659 (Commercial or FTS). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service at 1–800–877–8330, 24 hours a day, seven days a week, to contact Mr. Gage.

SUPPLEMENTARY INFORMATION: 5 CFR 1320.12(a) requires BLM to provide 60-day notice in the **Federal Register** concerning a collection of information contained in BLM Form 3100–12 to solicit comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. BLM will receive and analyze any comments sent in response to this notice and include them with its request for approval from the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

The Gas Well Data-Survey of Helium-Bearing Natural Gas, BLM Form 3100–12, provides for the gas sampling and analysis program used to locate helium occurrences in natural gases. BLM carries out this program under 74 Stat. 920, Public Law 104–273, Helium Privatization Act of 1996. The knowledge of helium occurrences is part of the Government's conservation program. BLM uses this information to evaluate the extent of any helium resources existing in the natural gas.

Without this information, BLM would not possess knowledge of the nature, location, and extent of domestic helium resources. The location and development of helium reserves and helium conservation and production are necessary to assure a supply of helium is available to the Federal Government.

Based on BLM's experience administering the activities described above, we estimate the public reporting burden for the information collected to average 15 minutes per response. The respondents include owners and operators of helium-bearing natural gas wells and transmission lines. The frequency of response is annual. The estimated number of responses per year is 200. The estimated total annual burden is 50 hours. BLM specifically requests your comments on its estimate of the amount of time that it takes to prepare a response.

BLM will summarize all responses to this notice and include them in the request for Office of Management and Budget approval. All comments will also become a matter of public record.

Dated: January 2, 2001.

Michael Schwartz,

BLM Information Collection Clearance Officer.

[FR Doc. 01–373 Filed 1–4–01; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–SJFO–01–0001EIS]

Notice of Availability of Draft Environmental Impact Statement

AGENCY: Bureau of Land Management.

ACTION: Notice of availability of the draft environmental impact statement oil and gas development on the southern Ute Indian reservation.

SUMMARY: Pursuant to 40 CFR 1500–1508, The Bureau of Land Management, in cooperation with the Bureau of Indian Affairs and the Southern Ute Indian Tribe, has prepared a comprehensive Draft Environmental Impact Statement to give Tribal leaders and agency decision-makers more comprehensive environmental impact information on which to base oil and gas leasing and development decisions. The document was prepared by a third party contractor chosen by BLM and its cooperators and funded by the agencies, the Southern Ute Tribe, and oil and gas lessees.

DATES: Written comments will be accepted on the Draft Environmental Impact Statement for a period until, on, or before March 6, 2001.

ADDRESSES: Please address questions, comments, or request for copies of the DEIS to the Bureau of Land Management, San Juan Field Office, Attn: Donald Englishman, 15 Burnett Court, Durango, CO 81310.

FOR FURTHER INFORMATION CONTACT: Donald Englishman at the above address or phone: 970–385–1346.

SUPPLEMENTARY INFORMATION: A limited number of individual copies of the DEIS may be obtained from the Bureau of Land Management, 15 Burnett Court, Durango, CO 81301.

Dated: December 20, 2000.

Calvin N. Joyner,

San Juan Field Office Manager, Colorado, Bureau of Land Management, USDI.

[FR Doc. 01–9 Filed 1–04–01; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–060–1220DM–00]

Notice of Availability

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) announces the

availability of a Final Off-Highway Vehicle (OHV) Environmental Impact Statement (EIS) and Proposed Plan Amendment. The Final EIS describes the analysis completed on proposed management changes in off-highway vehicle area designations on public lands administered by the Bureau of Land Management and Forest Service, Northern Region, in Montana, North Dakota, and portions of South Dakota. The BLM and Forest Service are joint lead agencies responsible for preparation of the final EIS. The purpose and need are to address the impacts of OHV travel on open areas that are currently available to motorized wheeled cross-country travel. The preferred alternative would restrict motorized wheeled cross-country travel yearlong on approximately 6 million acres of public land administered by the BLM and 10 million acres of National Forest System lands. These lands would be designated limited or restricted yearlong for motorized wheeled cross-country travel.

DATES: The proposed plan amendment is subject to a BLM 30-day protest period commencing with the date of publication of the Environmental Protection Agency's notice of availability in the **Federal Register**.

ADDRESSES: Written protests must be sent to: Director, Bureau of Land Management, Attention: Ms Brenda Williams, Protests Coordinator, WO–210/LS–1075, Department of the Interior, Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Jerry Majerus, 406–538–1924.

SUPPLEMENTARY INFORMATION: The Final EIS and Proposed Plan Amendment discloses the potential environmental consequences of managing motorized wheeled cross-country travel on public lands administered by the BLM and Forest Service, Northern Region, in Montana, North Dakota, and portions of South Dakota (excluding the Black Hills National Forest, Buffalo Gap Grasslands and the Fort Pierre Grasslands). A Draft OHV EIS and Plan Amendment was released for a 90-day public comment period in November 1999. Over 1,500 peopled attended 35 open houses that were held around Montana, North Dakota and South Dakota and 2,300 comment letters were received on the Draft OHV EIS and Plan Amendment.

Six alternatives, including a No Action Alternative, were analyzed in the Final OHV EIS and Proposed Plan Amendment. The No Action Alternative would maintain current management and areas currently open seasonally or yearlong to motorized wheeled cross-country travel would remain open. Alternatives 1, 2 and 5 would restrict motorized wheeled cross-country travel yearlong and the alternatives vary by exceptions allowed for cross-country travel. Alternative 3 would restrict motorized wheeled cross-country travel yearlong in North Dakota, most of Montana, and portions of South Dakota. Alternative 4 would limit motorized wheeled cross-country travel seasonally from September 1 to December 1 and February 16 to June 14. Alternative 5 is the preferred alternative.

Alternative 5, the preferred alternative, was developed in response to comments on the Draft OHV EIS and Plan Amendment from the public and other agencies. It restricts motorized wheeled cross-country travel yearlong throughout the analysis area to protect riparian areas, wetlands, crucial wildlife habitat, threatened or endangered species, soils and vegetation, aquatic resources, and to reduce user conflicts. Through subsequent site-specific planning, the BLM would designate roads and trails for motorized use. The following BLM resource management plans (Big Dry, Powder River, Billings, Headwaters, West HiLine, Judith-Valley-Phillips, North Dakota, and South Dakota) and the Dillon management framework plan would be amended to designate approximately 6 million acres limited yearlong for motorized wheeled cross-country travel under 43 CFR 8342.

The BLM's resource management planning process includes an opportunity for administrative review via a plan protest to the BLM's Director (43 CFR 1610.5–2). Any person who participated in the planning process and has an interest which is or may be adversely affected by the approval of an amendment to a resource management plan may protest such approval. Careful adherence to the following guidelines will assist in preparing a protest that will assure the greatest consideration to your point of view. Only those persons or organizations who participated in the planning process may protest. A protesting party may raise only those issues which were commented on during the planning process. New issues may be raised at any time but should be directed to the appropriate BLM field office for consideration in plan implementation, as potential plan amendments, or as otherwise appropriate. The protest period extends for 30 days. There is no provision for any extension of time. To be considered timely, your protest must be postmarked no later than the last day of the protest period. Also, although not a requirement, we suggest that you send your protest by certified mail, return receipt requested. In order to be considered complete, your protest must contain, at a minimum, the following information:

(1) The name, mailing address, telephone number and interest of the person filing the protest.

(2) A statement of the issue or issues being protested.

(3) A statement of the part or parts of the amendment being protested. To the extent possible, this should be done by reference to specific pages, paragraphs, sections, tables, maps, etc. included in the proposed amendment.

(4) A copy of all documents addressing the issue or issues submitted during the planning process by the protesting party or an indication of the discussion date of the issue(s) for the record.

(5) A concise statement explaining why the proposed decision is believed to be incorrect. This is a critical part of your protest. Take care to document all relevant facts. As much as possible, reference or cite the planning documents, environmental analysis documents, available planning records (i.e., meeting minutes or summaries, correspondence, etc.). A protest which merely expresses disagreement with the proposed decision, without any data will not provide us with the benefit of your information and insight. In this case, the Director's review will be based on the existing analysis and supporting data.

At the end of the 30-day protest period, the BLM may issue a Record of Decision, approving implementation of any portions of the proposed plan amendment not under protest. Approval will be withheld on any portion of the plan under protest until the protest has been resolved.

(Authority: Sec. 202, Pub. L. 94–579, 90 Stat. 2747 (43 U.S.C. 1712))

Dated: December 27, 2000.

Mat Millenbach,

State Director.

[FR Doc. 01–105 Filed 1–4–01; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM–930–1310–01; NMNM 0557388]

New Mexico: Proposed Reinstatement of Terminated Oil and Gas Lease

Under the provisions of Public Law 97–451, a petition for reinstatement of oil and gas lease NMNM 0557388 for lands in Rio Arriba County, New Mexico, was timely filed and was accompanied by all required rentals and

royalties accruing from April 1, 2000 the date of termination.

No valid lease has been issued affecting the lands. The lessee has agreed to new lease terms for rentals and royalties at rates of $5.00 per acre or fraction thereof and 16⅔ percent, respectively. The lessee has paid the required $500 administrative fee and has reimbursed the Bureau of Land Management for the cost of this **Federal Register** notice.

The Lessee has met all the requirements for reinstatement of the lease as set out in Sections 31(d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate the lease effective April 1, 2000, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

For further information contact: Gloria S. Baca, BLM, New Mexico State Office, (505) 438–7566.

Dated: December 18, 2000.

Gloria S. Baca,

Land Law Examiner.

[FR Doc. 01–289 Filed 1–4–01; 8:45 am]

BILLING CODE 4310–FB–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZA 28900]

Public Land Order No. 7251; Withdrawal of National Forest System Lands for State Highway 87 Roadside Zone; Arizona; Correction

Correction

In notice document 97–8627 on page 16179 in the issue of Friday, April 4, 1997, make the following correction:

On page 16179, in the first column, in the 24th line from the top, ''Sec. 9, SE¼SW¼ and SW¼SE¼;'' should read ''Sec. 9, W½''SE¼SW¼SE¼SE¼SW¼, and lot 6;''

Dated: December 19, 2000.

Elson F. Alvarez,

Acting Deputy State Director, Resources Division.

[FR Doc. 01–290 Filed 1–4–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–360–1230–PA–1220]

Supplementary Rules

AGENCY: Bureau of Land Management, Interior.

ACTION: Establishment of open hours for Reading Island Recreation Site, Swasey Drive-Area of Critical Environmental Concern (ACEC) and adjoining areas. The affected public land includes all BLM managed lands within:

Mount Diablo Meridian
T. 29N., R. 3W Sec. 3, 10
T. 31N., R. 5W Sec. 6, 7
T. 31N., R. 6W Sec. 12

SUMMARY: The BLM is prohibiting persons from driving, parking, or leaving motorized vehicles within the Reading Island Recreation Day Use Area, Swasey Drive ACEC and adjoining areas from 1 hour after sunset to 1 hour before sunrise. The use of these areas by motorized vehicles during the prohibited hours must have written authorization from a BLM authorized officer.

SUPPLEMENTARY INFORMATION: Reading Island Recreation Day Use Area, Swasey Drive ACEC and adjoining areas are recreation sites within Shasta County, California that are adjacent to residential areas. Although most public use at the site is lawful and orderly, night time vandalism, littering, shooting and drug use has been a problem. The night time activity deters lawful public use, damages natural and cultural resources, and creates a public nuisance. The BLM can reduce this type of unlawful activity and enhance the setting for valid recreation use by requiring a permit for night time motorized use. Reading Island Recreation Day Use Area, Swasey Drive ACEC and adjoining areas are open to the general public and motorized vehicles from 1 hour before sunrise until 1 hour after sunset. After those hours, visitors to the site must obtain written authorization from a BLM authorized officer to use motorized vehicles in the two areas mentioned. Written authorization will be in the form of a Special Recreation Use permit or equivalent instrument as determined by the BLM authorized officer. Law enforcement personnel and other public servants specifically authorized by the BLM are exempt from this closure. This closure shall remain in effect until further notice.

The authority for these closures and rule making is 43 CFR 8364.1. Any person who fails to comply with closure or restriction orders is subject to arrest and fines of up to $100,000 and/or imprisonment not to exceed 12 months. Unauthorized vehicles left at the Reading Island Recreation Site or the Swasey Drive ACEC and adjoining areas described while closed will be subject to towing at the owners expense.

DATES: This supplementary rule will take effect January 30th, 2000.

FOR FURTHER INFORMATION CONTACT: Charles Schultz, Field Manager, Redding Field Office, Bureau of Land Management, 355 Hemsted Drive, Redding, CA 96002 (530) 224–2100. For a period of 45 days from the date of publication of this notice, interested parties may submit written comments or objections to the Field Manager, Redding Field Office at the above address.

Dated: December 20, 2000.

Charles Schultz,

Field Manager.

[FR Doc. 01–44 Filed 1–4–01; 8:45 am]

BILLING CODE 4310–40–Q

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–958–1430–ET; HAG 01–0032; OR–23735]

Proposed Extension of Withdrawal and Opportunity for Public Meeting; Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) proposes to extend Public Land Order (PLO) 5980 for a 20 year period. This order withdrew public land from surface entry and mining, to protect the McDermitt Administrative Site and McDermitt Airport Protective Zone. The land has been and will remain open to mineral leasing. This notice also gives an opportunity to comment on the proposed action and to request a public meeting.

EFFECTIVE DATE: Comments and requests for a public meeting must be received by April 5, 2001.

ADDRESSES: Comments and meetings requests should be sent to the Oregon/Washington State Director, BLM, P.O. Box 2965, Portland, Oregon 97208–2965.

FOR FURTHER INFORMATION CONTACT: Charles R. Roy, BLM Oregon/Washington State Office, 503–952–6189.

SUPPLEMENTARY INFORMATION: On December 10, 1999, the Bureau of Land

Management, Vale District, requested that PLO 5980 be extended for an additional 20 year period. This withdrawal was made to protect the McDermitt Administrative Site and McDermtt Airport Protective Zone, and will expire on September 1, 2001.

The withdrawal comprises approximately 541.18 acres of public land in Malheur County. The land is located in Sections 12 and 13, T. 41 S., R. 42 E., and Sections 7 and 18, T. 41 S., R. 43 E., Willamette Principal Meridian and is described in PLO 5980. A complete description can be provided by the Oregon State Office at the address shown above.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed extension may present their views in writing to the Oregon\Washington State Director of the Bureau of Land Management.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with this proposed extension. Any interested persons who desire a public meeting regarding the proposed extension should submit a written request to the Oregon\Washington State Director of the Bureau of Land Management within 90 days from the date of publication of this notice. If the authorized officer determines that a public meeting will be held, a notice of time and place will be published in the **Federal Register** at least 30 days prior to the scheduled date of the meeting.

The extension will be processed in accordance with the regulations set forth in 43 CFR 2310.4.

Robert D. DeViney, Jr.,

Chief, Branch of Realty and Records Services.

[FR Doc. 01–388 Filed 1–4–01; 8:45 am]

BILLING CODE 4310–33–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–443]

In the Matter of Certain Flooring Products; Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 4, 2000 under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Alloc, Inc. of Racine Wisconsin, Berry Finance N.V. of Oostrozebeke, Belgium, and Valinge Aluminum, AB of Viken, Sweden. A supplement to the Complaint was filed on December 22, 2000. The complaint, as supplemented, alleges violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain flooring products by reason of infringement of claims 1–3, 5, 6, 8–12, 14, 15, 17–36, 38–40 and 41 of U.S. Letters Patent 5,860,267 and claims 1–14 of U.S. Letters Patent 6,023,907. The complaint further alleges that an industry in the United States exists and/or is in the process of being established as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after a hearing, issue a permanent exclusion order and permanent cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

FOR FURTHER INFORMATION CONTACT: James B. Coughlan, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202–205–2221. General information concerning the Commission may also be obtained by accessing its internet server *(http://www.usitc.gov).*

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2000).

Scope of Investigation

Having considered the complaint, the U.S. International Trade Commission, on December 27, 2000, *Ordered That*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain flooring products by reason of infringement of claims 1–3, 5, 6, 8–12, 14, 15, 17–36, 38–40 or 41 of U.S. Letters Patent 5,860,267 or claims 1–13 or 14 of U.S. Letters Patent 6,023,907, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Alloc, Inc., 3441 South Memorial Drive, Racine, Wisconsin 53403

Berry Financial N.V., Ingelmunstersteenweg 164, B–8780, Oostrozebeke, Belgium

Valinge Aluminium AB, Kyrkogranden 1, S–26040, Viken, Sweden

(b) The respondents are the following companies alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Unilin Decor N.V., Ooigemstraat 3, B–8710, Wielsbeke, Belgium

BHK of America, Inc., 11 Bond Street, Central Valley, NY 10917

Pergo, Inc., 3128 Highwoods Boulevard, Raleigh, NC 27604

Meister-Leisten Schulte GmbH, Meiste, Zum Walde 16, D–59602 Ruthen, Germany

Akzenta Paneele + Profile GmbH, Werner-Von-Siemens Str., 56759 Kaisersesch, Germany

Tarkett, Inc., 1139 Lehigh Avenue, Whitehall, Pennsylvania 18052

Roysol, 86, rue du fauborg Saint-Martin, F 89600 Saint Florentin, France

(c) James B. Coughlan, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Room 401–L, Washington, DC 20436, who shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, the Honorable Paul J. Luckern is designated as the presiding administrative law judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d) and 210.13(a) of the Commission's Rules, such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings, and may result in the issuance of a limited exclusion order or a cease and desist order or both directed against such respondent.

Issued: December 29, 2000.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–338 Filed 1–4–01; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

December 20, 2000.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of each individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation for BLS, ETA, PWBA, and OASAM contact Karin Kurz (202) 693–4127 or by E-mail to Kurz-Karin@dol.gov). To obtain documentation for ESA, MSHA, OSHA, and VETS contact Darrin King ((202) 693–4129 or by E-Mail to King-Darrin@dol.gov).

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for BLS, DM, ESA, ETA, MSHA, OSHA, PWBA, or VETS, Office of Management and Budget, Room 10235, Washington, DC 20503 (202) 395–7316), on or before February 5, 2001.

The OMB is particularly interested in comments which:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Type of Review: Extension of a currently approved collection.

Agency: Employment and Training Administration.

Title: Worker Profiling and Reemployment Services Activity and Worker Profiling and Reemployment Services Outcomes.

OMB Number: 1205–0353.

Affected Public: State, Local or Tribal government.

Frequency: Quarterly.

Number of Respondents: 53.

Estimated Time Per Respondent: 15 minutes each for the ETA 9048 and ETA 9049.

Total Burden Hours: 106.

Total annualized capital/startup costs: $0.

Total annual costs (operating/maintaining systems or purchasing services): $0.

Description: State Employment Security Agencies must provide a means of identifying claimants who are likely to exhaust benefits and refer such individuals to re-employment services to the extent that such services are available.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 01–324 Filed 1–4–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

December 28, 2000.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of each individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation for BLS, ETA, PWBA, and OASAM contact Karin Kurz ((202) 693–4127 or by E-mail to Kurz-Karin@dol.gov). To obtain documentation for ESA, MSHA, OSHA, and VETS contact Darrin King (202) 693–4129 or by E-Mail to King-Darrin@dol.gov).

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for BLS, DM, ESA, ETA, MSHA, OSHA, PWBA, or VETS, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395–7316), on or before February 5, 2001.

The OMB is particularly interested in comments which:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Type of Review: Extension of a currently approved collection.

Agency: Employment and Training Administration.

Title: Work Application/Job Order Recordkeeping.

*OMB Number:*1205–0001.

Affected Public: State, Local, or Tribal govt.

Number of Respondents: 52.

Estimated Time Per Respondent: 8 hours.

Total Burden Hours: 416 hours.

Total annualized capital/startup costs: $0.

Total annual costs (operating/maintaining systems or purchasing services): $0.

Description: The work application is used in State public employment service local offices for individuals seeking assistance in finding employment or employability development services. The job order is used in State public employment

service agencies to obtain information on employer job vacancies.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 01–325 Filed 1–4–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

December 18, 2000.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of each individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation for BLS, ETA, PWBA, and OASAM contact Karin Kurz ((202) 693–4127 or by E-mail to Kurz-Karin@dol.gov). To obtain documentation for ESA, MSHA, OSHA, and VETS contact Darrin King ((202) 693–4129 or by E-Mail to King-Darrin@dol.gov).

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for BLS, DM, ESA, ETA, MSHA, OSHA, PWBA, or VETS, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395–7316), on or before February 5, 2001.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submittion of responses.

Type of Review: Extension of a currently approved collection.

Agency: Employment Standards Administration (ESA).

Title: Application for Farm Labor Contractor or Farm Labor Contractor Employee Certificates of Registration.

OMB Number: 1215–0037.

Affected Public: Individuals or households; Business or other for-profit; and Farms.

Frequency: On occasion; Annually; and Biennially.

Number of Respondents: 9,200.

Number of Annual Responses: 9,200.

Estimated Time Per Response: 30 minutes.

Total Burden Hours: 4,600.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining sytstems or purchasing services): $2,153.

Description: The Migrant and Seasonal Agricultural Worker Protection Act provides that no individual may perform farm labor contracting activities without a certificate of registration. Form WH–530 is the application form that provides the Department of Labor with the information necessary to issue certificates specifying the farm labor contracting activities authorized.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 01–326 Filed 1–4–01; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determination in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain on expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of

Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

None.

Volume II

None.

Volume III

None.

Volume IV

None.

Volume V

None.

Volume VI

None.

Volume VII

None.

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon and Related Act.'' This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

The general wage determinations issued under the Davis-Bacon and related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the seven separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Signed at Washington, DC this 28th day of December 2000.

Terry Sullivan,

Acting Chief, Branch of Construction Wage Determinations.

[FR Doc. 01–223 Filed 1–4–01; 8:45 am]

BILLING CODE 4510–27–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–440]

FirstEnergy Nuclear Operating Company, Perry Nuclear Power Plant, Unit 1; Notice of Withdrawal of Application for Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of the FirstEnergy Nuclear Operating Company (the licensee) to withdraw its June 5, 2000, application for proposed amendment to Facility Operating License No. NPF–58 for the Perry Nuclear Power Plant, Unit 1, located in Lake County, Ohio.

The proposed amendment would have changed the Perry Nuclear Power Plant, Unit 1, as described in the Updated Safety Analysis Report. The proposed modification would have installed a time delay to the main turbine and feedwater pump turbine trip signal associated with a reactor core isolation cooling (RCIC) system automatic initiation.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the **Federal Register** on August 9, 2000 (65 FR 48747). However, by letter dated December 14, 2000, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated June 5, 2000, and the licensee's letter dated December 14, 2000, which withdrew the application for license amendment. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site (http://www.nrc.gov).

Dated at Rockville, Maryland, this 29th day of December, 2000.

For the Nuclear Regulatory Commission.

Douglas V. Pickett,

Senior Project Manager, Section 2, Project Directorate III, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 01–359 Filed 1–4–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. STN 50–454, STN 50–455, STN 50–456 and STN 50–457]

Commonwealth Edison Company, Byron Station, Units 1 and 2, Braidwood Station, Units 1 and 2; Environmental Assessment and Finding of no Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of amendments to Facility Operating License Nos. NPF–37, NPF–66, NPF–72 and NPF–77; issued to Commonwealth Edison Company (ComEd or licensee), for operation of Byron Station, Units 1 and 2 (Byron), located in Ogle County, Illinois, and Braidwood Station, Units 1 and 2 (Braidwood), located in Will County, Illinois.

Environmental Assessment

Identification of the Proposed Action

The proposed action would allow ComEd to increase the maximum reactor core power level from 3411 megawatts thermal (MWt) to 3586.6 MWt, which is an increase of 5 percent of rated core thermal power for each unit at Byron Station, Units 1 and 2, and for each unit at Braidwood Station, Units 1 and 2. The proposed action is in accordance with the licensee's application for amendment dated July 5, 2000, as supplemented on November 27, 2000.

The Need for the Proposed Action

The proposed action permits an increase in the licensed core thermal power from 3411 MWt to 3586.6 MWt and for each of the four units and provides the flexibility to increase the potential electrical output of Byron Station, Units 1 and 2, and Braidwood Station, Units 1 and 2.

Environmental Impacts of the Proposed Action

ComEd has submitted an environmental evaluation supporting the proposed power uprate and provided a summary of its conclusions concerning both the radiological and non-radiological environmental impacts of the proposed action.

Radiological Environmental Assessment: Radwaste Systems

The reactor coolant contains activated corrosion products, which are the result of metallic materials entering the water and being activated in the reactor region. Under power uprate conditions, the feedwater flow increases with power and the activation rate in the reactor region increases with power. The net result may be an increase in the activated corrosion product production. However, the evaluation has shown that the power uprate will not cause a significant change in the types or a significant increase in the amounts of any radiological effluent that may be released offsite.

Non-condensible radioactive gas from the main condenser, along with air in-leakage, normally contains activation gases (principally N–16, O–19 and N–13) and fission product radioactive noble gases. This is the major source of radioactive gas (greater than all other sources combined). These non-condensible gases, along with non-radioactive air, are continuously removed from the main condensers which discharge into the offgas system. The changes in gaseous effluents are small and are well within the uncertainty of the calculation of the original limits following implementation of the power uprate.

ComEd has concluded that there will be no significant change in the level of controls or methodology used for the processing of radioactive effluents; or handling of solid radioactive waste at Byron and Braidwood will not be impacted by operation at uprated power conditions, and the slight increase in effluents discharged would continue to meet the requirements of part 20 of Title 10 of the Code of Federal Regulations (10 CFR) and 10 CFR part 50, appendix I. Therefore, the power uprate will not appreciably affect the ability to process liquid or gaseous radioactive effluents and there are no significant environmental effects from radiological releases.

Dose Consideration

ComEd evaluated the potential effects of power uprate conditions on the radiation sources within the plant and the radiation levels during normal and post-accident conditions. The original calculations for determining the normal operational doses and radiation shielding requirements were very conservative and had additional margin assumed in the calculations. It was determined that these margins are sufficient to accommodate any increases attributed to the five percent increase in rated thermal power. The power uprate has no significant effect on plant normal operation radiation zones and shielding requirements. In addition, the normal operation component of the total integrated dose used for radiological equipment qualification (EQ) is not affected by the power uprate.

The power uprate does not involve significant increases in the offsite doses to the public from noble gases, airborne particulates, iodine, tritium, or liquid effluents. An upper bound analysis for the potential impact of the power uprate indicates that the increase in radiological releases and resultant dose impact is bounded by the percentage increase in the reactor core power. Therefore, the normal offsite doses are not significantly affected by operation at the uprated power level and remain below the limits of 10 CFR part 20 and 10 CFR part 50, appendix I.

The uprate program included a reanalysis or evaluation of all other aspects of large-break loss-of-coolant accident (LBLOCA), small-break loss-of-coolant accidents (SBLOCA), non-LOCA accidents, and Nuclear Steam Supply System (NSSS) and balance-of-plant (BOP) structures, systems, and components. Major NSSS components (*e.g.*, reactor pressure vessel, pressurizer, reactor coolant pumps, and steam generators); BOP components (*e.g.*, turbine, generator, and condensate and feedwater pumps); and major systems and sub-systems (*e.g.*, safety injection, auxiliary feedwater, residual heat removal, electrical distribution, emergency diesel generators, containment cooling, and the ultimate heat sink) have been assessed with respect to the bounding conditions expected for operation at the uprated power level. Control systems (*e.g.*, rod control, pressurizer pressure and level, turbine overspeed, steam generator level, and steam dump) have been evaluated for operation at uprated power conditions. Reactor trip and Engineered Safety Feature (ESF) actuation setpoints have been assessed and no needed changes were identified as a result of uprated power operations. The results of all of the above analyses and evaluations have yielded acceptable results and demonstrate that all design basis acceptance criteria will continue to be met during uprated power operations.

For post-accident conditions, the existing post-accident dose rate maps are adequate for power uprate conditions, and variances from existing calculated values are insignificant. The resulting radiation levels were determined to be within current regulatory limits, and there would be no effect on the plant equipment, access to vital areas, or habitability of the control room envelope and the Technical Support Center. The licensee has determined that access to areas requiring post-accident occupancy will not be significantly affected by the power uprate.

The calculated whole body and thyroid doses at the exclusion area boundary that might result from a postulated design basis LOCA were evaluated. All offsite doses evaluated at uprated power conditions remain below established regulatory limits. Therefore, the results of the radiological analyses remain below the 10 CFR part 100 guidelines and all radiological safety margins are maintained.

Non-Radiological Environmental Assessment

The licensee reviewed the non-radiological environmental impacts of the power uprate based on information submitted in the Environmental Report, Operating License Stage, the NRC Final Environmental Statement (FES), and the requirements of the Environmental Protection Plan. Based on this review, the licensee concluded that the proposed power uprate has no significant effect on the non-radiological elements of concern and the plant will be operated in an environmentally acceptable manner as established by the FES. In addition, the licensee states that existing Federal, State, and local regulatory permits presently in effect accommodate the power uprate without modification.

Byron Station Effluent Analysis and Evaluation

The Circulating Water (CW) System at Byron Station is a closed loop cooling system designed to dissipate waste heat from the turbine cycle to the atmosphere using natural draft cooling towers; one tower for each unit. Tower blowdown is accomplished by diverting flow from the circulating water system downstream of the CW pumps and upstream of the condenser and tower and discharging it to the Rock River.

The increase in heat associated with the power uprate will primarily affect the CW system and will be approximately 5 percent higher than the heat at the present power level. This will result in a 1 °F CW temperature increase. The current CW temperature rise is approximately 22 °F at 100 percent power. Although the National Pollutant Discharge Elimination System (NPDES) Permit does not specify a maximum cooling tower blowdown temperature, it controls temperature at the edge of the mixing zone in the river.

It has been determined that under a worst-case scenario, the tower blowdown temperature would be approximately 120 °F and has set this value as the administrative limit. Assuming a nominal summer river supply temperature of 70 °F − 90 °F and a cooling tower blowdown temperature of 96 °F, the proposed power uprate will not impact the 120 °F administrative limit.

Braidwood Station Effluent Analysis and Evaluation

The CW system at Braidwood Station is a closed loop cooling system similar to that at the Byron Station, except that waste heat is rejected from the turbine cycle to a cooling lake. Three CW pumps per unit pump cooling water from the lake to the main condenser. Discharge from the condenser is returned to the lake, where it is separated from the intake supply by a dike. The heat duty increase associated with power uprate is mainly associated with the CW System and will be approximately 5 percent higher than at the present power level. This will result in a 1 °F increase to the CW temperature rise, which is now approximately 21.8 °F at 100 percent power. The increase will nominally increase the lake temperature as the lake temperature is primarily influenced by climatic conditions.

Byron and Braidwood operate in compliance with a NPDES Permit, which requires all effluents to be closely monitored to assure compliance with the permit levels. There is no significant change in the types or a significant increase in the amounts of non-radiological effluents that may be released offsite due to the power uprate of each of the units at Byron Station, Units 1 and 2, and Braidwood Station, Units 1 and 2.

Noise Evaluation

The noise effects due to operation of Byron Station and Braidwood Station at uprated power conditions were reviewed. No increase in noise from the turbine or reactor building will result due to uprated power operations. In addition, the turbine and the reactor building supply and exhaust fans will continue to operate at current speeds, and the associated noise levels will also be unaffected by uprated power operations. In summary, the overall noise levels at Byron Station and Braidwood Station will not increase due to the power uprate.

The non-radiological environmental impacts related to the proposed power uprate at Byron Station and Braidwood Station have been reviewed and there are no adverse impacts or significant changes required to the current NPDES Permits or other plant administrative limits. No changes to land use would result and the proposed action does not involve any historic sites. Therefore, no new or different types of non-radiological environmental impacts are expected.

Summary

The proposed action will not significantly increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released off site, and there is no significant increase in occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action. With regard to potential nonradiological impacts, the proposed action does not involve any historic sites. It does not affect nonradiological plant effluents and has no other environmental impact. Therefore, there are no significant nonradiological environmental impacts associated with the proposed action. Accordingly, the NRC concludes that there are no significant environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

As an alternative to the proposed action, the staff considered denial of the proposed action (i.e., the ''no-action'' alternative). Denial of the application would result in no change in current environmental impacts, but would reduce the operational flexibility that would be afforded by the proposed change. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Final Environmental Statement for the Byron Station, Units 1 and 2, and in the Final Environmental Statement for Braidwood Station, Units 1 and 2.

Agencies and Persons Consulted

In accordance with its stated policy, on December 18, 2000, the staff consulted with the Illinois State official, Frank Niziolek of the Illinois Department of Nuclear Safety, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated July 5, 2000, as supplemented on November 27, 2000. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the ADAMS Public Library component on the NRC Web site, *http://www.nrc.gov* (the Electronic Reading Room).

Dated at Rockville, Maryland, this 22nd day of December 2000.

For the Nuclear Regulatory Commission.

Anthony J. Mendiola,

Chief Section 2, Project Directorate III, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 01–360 Filed 1–4–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

NRC Coordination Meeting With Standards Development Organizations

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Meeting.

SUMMARY: The NRC will host a coordination meeting with key standards development organizations (SDOs) and other stakeholders. These meetings have been held approximately semi-annually as part of the NRC's commitment to utilize consensus standards to increase the involvement of licensees and others in the NRC's regulatory development process. This is consistent with the provisions of Public Law (Pub. L.) 104–113, the National Technology and Transfer Act of 1995, and Office of Management and Budget (OMB) Circular A–119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment.'' The primary purpose of these meetings is to foster better communication between SDOs' and NRC regarding standards development and their use. This notice provides the date and agenda for the next meeting.

DATES: January 17, 2001—The meeting will begin at 1:00 p.m. and will last approximately four hours. Attendees should enter the One White Flint North

lobby by 12:45 p.m. to complete the required badging process.

Location: U.S. Nuclear Regulatory Commission Headquarters, One White Flint North, 11555 Rockville Pike, Room O–4–B4, Rockville, Maryland 20852–2738.

Contact: Wallace E. Norris, USNRC, Telephone: (301) 415–6796; Fax: (301) 415–5074; Internet: wen@nrc.gov.

Attendance: This meeting is open to the general public. All individuals planning to attend, including SDO representatives, are requested to preregister with Mr. Norris by telephone or e-mail and provide their name, affiliation, phone number, and e-mail address.

Program: The purpose of the meeting is to foster better communication between SDOs and NRC regarding standards development and use. By holding periodic coordination meetings, the SDOs will be able to describe their on-going and planned activities, and the NRC will be able to discuss activities and issues related to specific standards that are being developed or revised to meet its regulatory needs. The meeting will be coordinated by the NRC Standards Executive.

Among the topics to be discussed are:

NRC standards needs
Status of on-going SDO efforts
ANS presentation regarding the possible development of three standards:
  Risk-based fire
  Component reliability
  Non-reactor facility PRA
Verifying accuracy of SDO and NRC rosters

Dated in Rockville, Maryland this 29th day of December, 2000.

For the Nuclear Regulatory Commission,

Michael E. Mayfield,

NRC Standards Executive.

[FR Doc. 01–358 Filed 1–4–01; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549

Extension: Rule 12g3–2, OMB Control No. 3235–0119, SEC File No. 270–104; Rule 7a–15 thru 7a–37, OMB Control No. 3235–0132, SEC File No. 270–115; Rule 13e–1, OMB Control No. 3235–0305, SEC File No. 270–255

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget requests for extension of the previously approved collections of information discussed below.

Rule 12g3–2 (OMB 3235–0119; SEC File No. 270–104) provides an exemption from Section 12(g) of the Securities Exchange Act of 1934 (Act) for foreign private issuers. Rule 12g3–2 is designated to provide investors in foreign securities with information about such securities and the foreign issuer. It affects approximately 1, 800 foreign issuer respondents at an estimated one burden hour per response for a total annual burden of 1,800 hours. All information required by Rule 12g3–2 is available to the public. All information provided under Rule 12g3–2 is mandatory.

Rules 7a–15 through 7a–37 (OMB 3235–0132; SEC File No. 270–115) sets forth the general requirements relating to applications, statements and reports that must be filed under the Trust Indenture Act of 1939 by issuers and trustees qualifying indentures for offerings of debt securities. Rules 7a–15 through 7a–37 are disclosure guidelines and do not directly result in any collection of information. The respondents are persons and entities subject to Trust Indenture Act requirements. No information collection burdens are imposed directly by these rules so they are assigned only one burden hour for administrative convenience.

Rule 13e–1 (OMB 3235–0305; SEC File No. 270–255) makes it unlawful for an issuer who has received notice that it is subject of a tender offer made under 14(d)(1) of the Act and that has commenced under Rule 14d–2 to purchase any of its equity securities during the tender offer unless it first files a statement with the Commission containing information require by the Rule. This rule is in keeping with the Commission's statutory responsibility to prescribe rules and regulations that are necessary for the protection of investors. Public companies are the respondents. An estimated 20 respondents file Rule 13e–1 submissions annually at an estimated 13 hours per response for a total annual burden of 260 hours. All information provided is made available to the public.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Written comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503; and (ii) Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Comments must be submitted to OMB within 30 days of this notice.

Dated: December 27, 2000.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–313 Filed 1–4–00; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–27332]

Filings Under the Public Utility Holding Company Act of 1935, as amended (''Act'')

December 29, 2000.

Notice is hereby given that the following filing has been made with the Commission pursuant to provisions of the Act and rules promulgated under the Act. All interested persons are referred to the application for a complete statement of the proposed transaction summarized below. The application and any amendments are available for public inspection through the Commission's Branch of Public Reference.

Interested persons wishing to comment or request a hearing on the application should submit their views in writing by January 23, 2001, to the Secretary, Securities and Exchange Commission, Washington, DC 20549–0609, and serve a copy on the relevant applicants at the address specified below. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of facts or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After January 23, 2001, the application as filed or as amended may be granted.

AES Corporation, Dennis W. Bakke and Roger W. Sant (70–9779)

The AES Corporation (''AES''), an electric public-utility holding company exempt from registration under section

3(a)(5) of the Act,[1] Dennis W. Bakke and Roger W. Sant, all at 1001 North 19th Street, Arlington, VA 22209, have filed an application (''Application'') under sections 9(a)(2) and 3(a)(5) of the Act.

AES requests approval of its proposal acquisition of all of the equity securities of IPALCO Enterprises, Inc., (''IPALCO''), an electric and gas public-utility holding company exempt from registration under section 3(a)(1) by rule 2. AES also requests an order under section 3(a)(5) exempting it from all provisions of the Act other than section 9(a)(2) following its acquisition of IPALCO.

Dennis W. Bakke and Roger W. Sant, are, respectively, AES's President and Chief Executive Officer, and the Chairman of its Board of Directors. Each owns more than 5% of AES's common stock. They request approval of their indirect acquisition of interests in IPALCO.

AES, incorporated in Delaware, is a United States-based multinational electric power generation and energy distribution company with operations in sixteen countries worldwide. AES currently owns all of the common stock of CILCORP Inc. (''CILCORP''), an Illinois public-utility holding company exempt from registration under section 3(a)(1) by rule 2, and the parent of Central Illinois Light Company (''CILCO''), an electric and gas utility company. CILCO is engaged in the generation, transmission, distribution and sale of electric energy in an area of approximately 3,700 square miles in central and east-central Illinois, and the purchase, distribution, transportation and retail sale of natural gas in an area of approximately 4,500 square miles also in central and east-central Illinois.

AES is engaged principally in the development, ownership and operation of electric generating plants and electric and gas distribution companies. With the exception of CILCO, all AES plants and companies are, or are owned by, exempt wholesale generators (as defined in section 32 of the Act), foreign utility companies (as defined in section 33 of the Act), or qualifying facilities under the Public Utility Regulatory Policies Act of 1978. On an actual *pro rata* consolidated basis as of December 31, 1999, over 97% of AES' revenues for that year were from electric generation and distribution activities. AES's other activities include the sale of steam and other commodities connected with its cogeneration operations, as well as operational, construction and project development services, and gas and power marketing.

IPALCO has one public-utility subsidiary, Indianapolis Power & Light Company (''IPL''), which is principally engaged in the generation, transmission, distrubiton and sale of electric energy in a region of central Indiana within about forty miles of the city of Indianapolis, and the sale of steam within a limited area in that city. As of December 31, 1999, IPL served approximately 433,025 retail electric customers, and its electric utility assets totaled $1.9 billion. For the year 1999 its electric utility revenues were $800.4 million. IPL owns and operates three primarily coal-fired electric generating plants, one coal and gas-fired steam production plant, and a separately sited gas-fired combustion turbine. These facilities have a total gross nameplate rating of 3,104 megawatts, and a gross steam generation capacity of 1,990 megapounds per hour.

Under an Agreement and Plan of Share Exchange (''Share Exchange Agreement'') dated as of July 15, 2000, between AES and IPALCO, the two companies propose to effect a share exchange through which IPALCO will become a wholly owned subsidiary of AES (''Transaction''). Each outstanding share of IPALCO common stock would be converted into the right to receive shares of AES common stock with a market value of $25.00 (subject to adjustment as described in the Share Exchange Agreement). Following the Transaction, AES would own IPALCO as a first-tier subsidiary, and IPALCO's direct and indirect subsidiaries, including IPL, will retain their current relationship with IPALCO. IPALCO would continue to claim exemption under section 3(a)(1) by rule 2.

AES states it will commit to enter into an agreement with an unaffiliated person within three years from completion of the Transaction to divest its ownership of all utility assets of CILCO subject to the jurisdiction of the Commission. AES states that it has held preliminary discussions with potential acquirors of CILCO's utility assets. Upon completion of this divestiture, IPL would be the only public-utility subsidiary of AES.

AES further asserts that it will qualify for the requested exemption under section 3(a)(5) of the Act following the Transaction because it will not derive a material part of its income, directly or indirectly, from one or more companies whose principal business within the United States is that of a public-utility company.

Mr. Bakke and Mr. Sant owns 8.31 percent and 9.94 percent, respectively, of AES's common stock. They are thus indirect affiliates, as defined in section 2(a)(11)(a) of the Act, of CILCO, and as a result of the Transaction, would become indirect affiliates of IPL. They request approval under sections 9(a)(2) and 10 of their acquisition, through AES, of an indirect interest in IPL.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–314 Filed 1–4–01; 8:45 am]

BILLING CODE 8010–01–M

[1] Holding Co. Act Release No. 27063 (August 20, 1999).

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–24811]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

December 28, 2000.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of December 2000. A copy of each application may be obtained for a fee at the SEC's Public Reference Branch, 450 Fifth St., NW., Washington, DC 20549–0102 (tel. 202–942–8090). An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 22, 2001, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549–0609. For Further Information Contact: Diane L. Titus, at (202) 942–0564, SEC, Division of Investment Management, Office of Investment Company Regulation, 450 Fifth Street, NW., Washington, DC 20549–0506.

The Winter Harbor Fund [File No. 811–8793]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On October 13, 2000, applicant transferred its assets to The Royce Total Return Fund, a series

of The Royce Fund, based on net asset value. Expenses of $29,109 were incurred in connection with the reorganization, of which Royce & Associates, Inc., investment adviser to the acquiring fund, paid $25,000, Ebright Investments, Inc., applicant's investment adviser, paid $1,244, and applicant paid the remainder.

Filing Dates: The application was filed on November 9, 2000, and amended on December 15, 2000.

Applicant's Address: 511 Congress Street, Portland, Maine 04101.

Advisers Managers Trust [File No. 811–8578]

Summary: Applicant, a master fund in a master/feeder structure, seeks an order declaring that it has ceased to be an investment company. On May 1, 2000, applicant made a liquidating distribution to its shareholders based on net asset value. Expenses of $58,000 incurred in connection with the liquidation were paid by applicant.

Filing Dates: The application was filed on November 16, 2000, and amended on December 19, 2000.

Applicant's Address: 605 Third Avenue, 2nd Floor, New York, New York 10158–0180.

ESC Strategic Funds, Inc. [File No. 811–8166]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On March 24 and March 27, 2000, applicant transferred its assets to STI Classic Funds based on net asset value. Expenses of $71,807 incurred in connection with the reorganization were paid by each series of applicant on a pro rata basis.

Filing Dates: The application was filed on July 31, 2000, and amended on October 20, 2000.

Applicant's Address: 3435 Steltzer Road, Columbus, Ohio 43219.

Jardine Fleming Asia Infrastructure Fund, Inc. [File No. 811–8458]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make any public offering or engage in business of any kind.

Filing Dates: The application was filed on October 25, 2000, and amended on December 11, 2000.

Applicant's Address: 1345 Avenue of the Americas, New York, New York 10105.

Van Kampen Convertible Securities Fund [File No. 811–2282]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On August 9, 2000, applicant transferred its assets to Van Kampen Harbor Fund based on net asset value. Expenses of $175,100 incurred in connection with the reorganization were paid by applicant.

Filing Dates: The application was filed on October 25, 2000, and amended on December 4, 2000.

Applicant's Address: 1 Parkview Plaza, PO Box 5555, Oakbrook Terrace, Illinois 60181–5555a.

Worldwide Developing Resources Portfolio [File No. 811–8151]

Summary: Applicant, the master fund in a master/feeder structure, seeks an order declaring that it has ceased to be an investment company. On December 18, 1999, applicant made a final liquidating distribution to its shareholders based on net asset value. Expenses of $25,297 incurred in connection with the liquidation were paid by Eaton Vance Worldwide Developing Resources Fund, a feeder fund that invested all of its assets in applicant.

Filing Dates: The application was filed on November 1, 2000, and amended on November 29, 2000.

Applicant's Address: The Eaton Vance Building, 255 State Street, Boston, Massachusetts 02109.

Great Plains Fund [File No. 811–8281]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On September 8, 2000, applicant transferred its assets to Wells Fargo Funds Trust based on net asset value. Applicant bore no expenses in connection with the reorganization.

Filing Dates: The application was filed on November 14, 2000, and amended on December 22, 2000.

Applicant's Address: 5800 Corporate Drive, Pittsburgh, Pennsylvania 15237–7010.

Michigan Daily Municipal Income Fund, Inc. [File No. 811–5015]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On October 23, 2000, applicant made a final liquidating distribution to its sole shareholder based on net asset value. Expenses of $3,000 incurred in connection with the liquidation were paid by Reich & Tang Asset Management L.P., applicant's investment adviser.

Filing Dates: The application was filed on December 6, 2000, and amended on December 22, 2000.

Applicant's Address: 600 Fifth Avenue, New York, New York 10020.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–293 Filed 1–4–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43777; File No. SR–CHX–00–39]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 by the Chicago Stock Exchange, Incorporated Relating to Membership Dues and Fees During the E-Session

December 28, 2000.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 18, 2000, the Chicago Stock Exchange, Incorporated (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. On December 19, 2000, the CHX amended the proposal.[3] The Exchange has designated this proposal as one establishing or changing a due, fee, or other charge imposed by the CHX under Section 19(b)(3)(A)(ii) of the Act,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its membership dues and fees schedule (the ''Schedule'') to continue, through June 30, 2001, (i) the credit program that provides Exchange specialists and floor

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* December 18, 2000 letter from Ellen J. Neely, Vice President and General Counsel, CHX, to Nancy J. Sanow, Assistant Director, Division of Market Regulation, SEC (''Amendment No. 1''). In Amendment No. 1, the CHX provided a revised Exhibit A to the proposed rule change. The CHX inadvertently omitted the text relating to the extension of the E-Session credit program in the original version of Exhibit A. For purposes of calculating the 60-day abrogation period, the Commission considers the period to begin as of the date the CHX filed Amendment No. 1 (December 19, 2000).

[4] 15 U.S.C. 78s(b)(3)(A)(ii).

brokers with a credit of $.25 per trade executed during the Exchange's E-Session extended hours trading session; and (ii) the waiver of all transaction, order processing and floor broker fees for transactions that occur during the E-Session. The text of the proposed rule change is available upon request from the CHX and the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The CHX proposes to amend the Schedule to eliminate, through June 30, 2001, order processing, transaction and floor broker fees for transactions that occur during the E-Session.[5] This proposal is designed to allow CHX members to continue to participate in the E-Session without incurring the fees normally associated with their CHX transactions.[6] According to the Exchange, the vast majority of the securities that trade during the E-Session are already subject to order processing and transaction fee waivers under the current fee schedule because they are either Nasdaq/NMS issues or issues within the S&P 500. Waiving fees on the few remaining securities and on floor broker transactions in all securities simplifies the Exchanges' fee-related communication with its members.

Additionally, this proposal would extend the current E-Session credit program through June 30, 2001. Exchange management developed this program to encourage members to seek additional order flow during the E-Session. Under the program, Exchange specialists and floor brokers receive a credit of $.25 per trade executed during the E-Session. This credit program was approved in May 2000,[7] and has been extended through December 31, 2000.[8]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act[9] in that it provides for the equitable allocation of reasonable dues, fees and other charges among its members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Act

The proposed rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[10] and subparagraph (f) of Rule 19b–4 thereunder,[11] because it involves a due, fee, or other charge. At any time with 60 days of the filing of the proposed rule change,[12] the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and coping in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to file number SR–CHX–00–39, and should be submitted by January 25, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–316 Filed 1–4–01; 8:45 am]

BILLING CODE 8010–01–M

[5] On October 13, 1999, the Commission approved, on a pilot basis, the CHX's proposed rule change that allowed the CHX to implement an extended hours trading session. *See* Securities Exchange Act Release No. 42004 (October 13, 1999), 64 FR 56548 (October 20, 1999) (SR–CHX–99–16). The Commission recently approved the CHX's proposal to make the E-Session a permanent part of the CHX's operations. *See* Securities Exchange Act Release No. 43304 (September 19, 2000), 65 FR 57850 (SR–CHX–00–26). The E-Session takes place from 3:30 p.m. to 5:30 p.m., Central Time, Monday through Friday.

[6] E-Session fees have been waived since the beginning of the E-Session. *See* Securities Exchange Act Release Nos. 42089 (November 2, 1999), 64 FR 60864 (November 8, 1999) (SR–CHX–99–23) (waiving fees from October 13, 1999 through December 31, 1999); 42329 (January 11, 2000), 65 FR 3000 (January 19, 2000) (SR–CHX–99–29) (waiving fees from January 1, 2000 through March 1, 2000); 42486 (March 2, 2000), 65 FR 12601 (March 9, 2000) (SR–CHX–005) (waiving fees from March 2, 2000 through June 30, 2000); and 42929 (June 13, 2000), 65 FR 38620 (June 21, 2000) (SR–CHX–00–18) (waiving fees from July 1, 2000 through October 1, 2000); and 43403 (October 2, 2000), 65 FR 60234 (October 10, 2000) (SR–CHX–00–30) (waiving transaction, order processing and floor broker fees through December 31, 2000). This proposal extends the waiver of the same fees through June 30, 2001.

[7] *See* Securities Exchange Act Release No. 42784 (May 15, 2000), 65 FR 33383 (May 23, 2000) (SR–CHX–00–12).

[8] *See* Securities Exchange Act Release No. 43402 (October 2, 2000), 65 FR 25867 (October 6, 2000) (SR–CHX–00–29).

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 240.19b–4(f)(2).

[12] The Commission considers the proposal to have been filed as of December 19, 2000. *See* footnote 3, *supra.*

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43778; File No. SR–CHX–00–38]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Chicago Stock Exchange, Incorporated Relating to Membership Dues and Fees

December 28, 2000.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4[2] thereunder, notice hereby is given that on December 18, 2000, the Chicago Stock Exchange, Incorporated (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CHX proposes to amend its membership dues and fees schedule (''Schedule''), effective January 1, 2001, to: (1) Increase the special fixed fees for Nasdaq/NMS securities; (2) assess a new fixed fee on ''dedicated odd-lot dealers''; (3) revise the fees for transactions in listed securities executed through a floor broker; (4) raise the cap on the maximum transaction fees that can be incurred by a member firm; and (5) increase the earned credits available through the floor broker credit program. Additionally, the Exchange proposes to reconfigure its Schedule to include all of its transaction fees in one portion of the Schedule. The proposed rule change is available at the principal office of the CHX and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received regarding the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

A. Purpose

The proposed rule change amends the Schedule in several ways. These changes are designed to allow the Exchange to continue its exponential growth while providing a strong market for its members and for investors.

First, the proposal would increase the specialist fixed fees for Nasdaq/NMS Securities and assess a new fixed fee on ''dedicated odd-lot dealers.'' The specialist fixed fee for Nasdaq/NMS Securities is paid by the specialist in each particular security; the amount of the fee is based on a market share calculation in that security.[3] The new dedicated odd-lot dealer fee is a flat fee assessed on any odd-lot dealer (as defined in Article XXXI, Rule 3 of the Exchange's Rules) whose principal business is the trading of odd-lots.[4]

The proposal also makes changes to the CHX's transaction fee schedule by: (a) Setting a flat per share fee, instead of a graduated fee based on the number of shares traded, for agency transactions in Dual Trading System Securities that are executed through a floor broker; and (b) raising the current caps on transaction fees paid by member firms.[5]

Additionally, the proposal would revise the floor broker credit program by increasing the earned credits available under the program and by providing that the Exchange will pay floor brokers for any unused credits each month. This credit program is designed to stimulate growth on the Exchange, enhance the competitive capability of floor brokers, and foster cooperation on the Exchange's trading floor by rewarding floor brokers for their work to increase Exchange revenue.

Finally, the proposed would reconfigure the Schedule to include all of its transaction fees in one section of the Schedule.

2. Statutory Basis

The CHX believes that the proposed rule change is consistent with Section 6(b)(4) of the Act[6] in that it provides for the equitable allocation of reasonable dues, fees, and other charges among its members.

[3] The fixed fee for Nasdaq/NMS Securities was first assessed in April 2000. Before that date, the Exchange had charged its members a fixed fee on Dual Trading System Securities (securities listed on the New York Stock Exchange or the American Stock Exchange) for many years. The Nasdaq/NMS-related fixed fees allow the Exchange to at least partially defray the costs associated with the continued development and anticipated growth of its Nasdaq/NMS program. The Exchange originally began assessing a Nasdaq/NM Securities fixed fee at a somewhat lower level than the fee that had been in place for Dual Trading System Securities to allow members time to adjust their business models to this new requirement. Now, nine months later, the Exchange proposes to increase the fee to more closely resemble the one charged for Dual Trading System Securities.

[4] This fee is designed to at least partially defray the costs associated with the continued development and anticipated growth of the Exchange's odd-lot program.

[5] Under the current Schedule, firms are subject to either a $78,000 or $54,000 cap on transaction fees for orders that are not sent through the Exchange's MAX® trading system, depending upon whether or not the firm has a market maker or floor broker presence. The revised Schedule would remove the reference to a floor presence and impose separate $110,000 caps on non-MAX transaction fees for transactions in Nasdaq/NMS Securities and in dual Trading System Securities.

[6] 15 U.S.C. 78f(b)(4).

B. Self-Regulatory Organization's Statement of Burden on Competition

The CHX does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change establishes or changes a due, fee, or other charge imposed by the Exchange and therefore has become effective pursuant to Section 19(B)(3)(A)(ii) of the Act[7] and subparagraph (f)(2) of Rule 19b–4[8] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–CHX–00–38 and should be submitted by January 26, 2001.

[7] 15 U.S.C. 78f(b)(3)(A)(ii).

[8] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–317 Filed 1–4–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43776; File No. SR–PHLX–00–103]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto by the Philadelphia Stock Exchange, Inc. Relating to Proposed Fees for Processing of Units of Beneficial Interest in the Nasdaq-100 Trust, Series 1

December 28, 2000.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 8, 2000, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. On December 14, 2000, the Exchange submitted Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its fee schedule to accommodate the trading of Units of Beneficial Interest in the Nasdaq 100 Trust, Series 1 (''Nasdaq-100 Index Tracking Stock''), traded under the symbol and widely known as QQQ. On June 14, 2000, the Phlx filed a proposed rule change with the Commission to permit, among other things, the trading pursuant to unlisted trading privileges (''UTP''), of Nasdaq-100 Index Tracking Stock.[4] The proposal has been approved.[5] In addition, the Exchange has obtained a license to use the Nasdaq-100 Index in connection with the trading of the Nasdaq-100 Index Tracking Stock.[6]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Phlx included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Phlx has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to provide for fees that will apply to trading on the Exchange of Units of Beneficial Interest in the Nasdaq 100 Trust, Series 1, referred to as ''Nasdaq 100 Shares.'' Specifically, under the Exchange's proposal the Exchange will assess no charge to members for trades entered through the Phlx Automated Communication and Execution System (''PACE''), but will impose a $1.00 fee for non-PACE trades.[7] Specialists will be charged a fee of $0.002 per share, with a maximum charge of $50.00 per trade, whether or not a trade takes place on PACE.[8] No other Phlx transaction fees will apply to trades in Nasdaq-100 Index Tracking Stock. The Exchange represents that, upon initiation of trading, members will be notified, by means of a circular, of the new fees applicable to trading in Nasdaq-100 Index Tracking Stock.

The Exchange represents that the fees proposed above for transactions in Nasdaq-100 Index Tracking Stock are lower than the fees charged for other equities already traded on the Exchange. The Phlx believes that the proposed lower fees should encourage trading of Nasdaq-100 Index Tracking Stock, while ensuring that the amounts collected will still cover the Exchange's costs of administering the trading of this new product. The Exchange further states that lower fees should also provide market participants with a more affordable market for the trading of this product. The Phlx states that a more affordable, competitive market for trading should attract more order flow in Nasdaq-100 Index Tracking Stock to the Exchange, which in turn should further increase liquidity of Nasdaq-100 Index Tracking Stock, and create a tighter, more liquid market. The Phlx represents that increased market competition should both benefit investors and protect the public interest in general.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section (6)(b)(4) [10] in particular because it applies equally to all members that would be trading the Nasdaq-100 Index Tracking Stock and, therefore, is an equitable allocation of reasonable fees among Exchange members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Phlx represents that it does not believe the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

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[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange: replaced the term ''Nasdaq-100 Shares'' with ''Nasdaq-100 Index Tracking Stock'' noted that ''Nasdaq-100 Index Tracking Stock'' and ''QQQ'' are service marks of the Nasdaq Stock Market, Inc. (''Nasdaq'') and that the Phlx has entered into a licensing agreement with Nasdaq to use those marks for certain purposes; observed that the Commission has approved a related rule filing, File No. SR–Phlx–00–54, relating to the listing and trading of Trust Shares; clarified that a fee for trades not processed through the Phlx Automated Communication and Execution System (''PACE'') will be paid by members of the Exchange; and clarified that the Phlx will charge specialists a per-share fee whether or not an order is executed via PACE. *See* letter from Carla Behnfeldt, Counsel, Phlx, to Nancy Sanow, Assistant Director, Division of Market Regulation, Commission, dated December 14, 2000 (''Amendment No. 1'').

[4] File No. SR–Phlx–00–54.

[5] Securities Exchange Act Release No. 43717 (December 13, 2000). The proposal is pending publication in the **Federal Register**.

[6] The Nasdaq-100®, Nasdaq-100 Index®, Nasdaq®, The Nasdaq Stock Market®, Nasdaq-100 Shares℠, Nasdaq-100 Trust℠, Nasdaq-100 Index Tracking Stock℠, and QQQ℠, are trademarks or service marks of The Nasdaq Stock Market, Inc. (''Nasdaq'') and have been licensed for use for certain purposes by the Phlx pursuant to a License Agreement with Nasdaq. The Nasdaq-100 Index® (''Index'') is determined, composed, and calculated by Nasdaq without regard to the Licensee, the Nasdaq-100 Trust™, or the beneficial owners of Nasdaq-100 Shares℠. Nasdaq has complete control and sole discretion in determining, comprising or calculating the Index or in modifying in any way its method for determining, comprising or calculating the Index in the future.

[7] The $1.00 fee for non-PACE trades will be paid by a member who is trading with a specialist, either for the member's own account or for the account of the member's customer. *See* Amendment No. 1, *supra* note 3.

[8] *Id.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78s(b)(4).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [11] and Rule 19b–4(f)(2) thereunder [12] because it establishes or changes a due, fee, or other charge imposed by the self-regulatory organization. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[13]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Phlx. All submissions should refer to File No. SR–Phlx–00–103 and should be submitted by January 26, 2001.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[14]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–312 Filed 1–4–01; 8:45 am]

BILLING CODE 8010–01–M

[11] 15 U.S.C. 78s(b)(3)(A)(ii).

[12] 17 CFR 240.19b–4(f)(2).

[13] 15 U.S.C. 78s(b)(3)(C).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43781; File No. SR–SCCP–00–05]

Self-Regulatory Organization; Stock Clearing Corporation of Philadelphia; Notice of Filing and Order Granting Accelerated Approval on a Temporary Basis of a Proposed Rule Change Extending Approval of Restructured and Limited Clearing Services

December 28, 2000.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on December 6, 2000, the Stock Clearing Corporation of Philadelphia (''SCCP'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which items have been prepared primarily by SCCP. The Commission is publishing this notice and order to solicit comments from interested persons and to grant accelerated approval of the proposal.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

SCCP proposes to extend, for a one year period ending December 31, 2001, the ability to provide limited clearance and settlement services. Specifically, SCCP seeks to continue to provide trade confirmation and recording services for members of the Philadelphia Stock Exchange, Inc. (''Phlx'') effecting transactions through Regional Interface Operations (''RIO'') and ex-clearing accounts. SCCP will also continue to provide margin accounts to certain participants cleared through an account established by SCCP at the National Securities Clearing Corporation (''NSCC'').

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, SCCP included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth is sections (A), (B), and (C) below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78S(b)(1).

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to continue SCCP's restructured business for an additional one year period through December 31, 2001.

Background

In an Agreement dated as of June 18, 1997, by and among the Phlx, SCCP, Philadelphia Depository Trust Company (''Philadep''), NSCC, and The Depository Trust Company (''DTC''), Philadep and SCCP agreed to certain provisions, including that: (i) Philadep would cease providing securities depository services; (ii) Philadep would make available to its participants access to the facilities of one or more other organizations providing depository services; (iii) SCCP would make available to SCCP participants access to the facilities of one or more other organizations providing securities clearing services; and (iv) SCCP would transfer to the books of such other organizations the CNS system open positions of SCCP participants on the books of SCCP.

In December, 1997, the Commission approved a proposed rule change which gave effect to the Agreement and which reflected Philadep's withdrawal from the depository business and SCCP's restructured and limited clearance and settlement business.[2] At that time, the Commission stated that ''because a part of SCCP's proposed rule change concerns the restructuring of SCCP's operations to enable SCCP to offer limited clearing and settlement services to certain Phlx members, the Commission finds that it is appropriate to grant only temporary approval to the portion of SCCP's proposed rule change that amends SCCP's By-laws, Rules, or Procedures. This will allow the Commission and SCCP to see how well SCCP's restructured operations are functioning under actual working conditions and to determine whether any adjustments are necessary. Thus, the Commission is approving the portion of SCCP's proposal that amends its By-laws, Rules, or Procedures through December 31, 1998.'' In December 1998 and December 1999, one year extensions of such approval were granted by the Commission to allow SCCP to continue its restructured and

[2] Securities Exchange Act Release No. 39444 (December 11, 1997), 62 FR 66703 [File Nos. SR–SCCP–97–04, SR–DTC–97–16, SR–NSCC–97–08, and SR–Philadep–97–04].

limited clearance and settlement services.[3]

SCCP is hereby requesting that the Commission extend its approval of SCCP's restructured and limited clearance and settlement services for an additional year. SCCP believes that such extension is appropriate so that it may continue to offer its limited clearance and settlement services to its participants. SCCP believes that its restructured operations have functioned consistent with the original proposed rule change and SCCP will continue to evaluate whether any adjustments are necessary.

Purpose

In the original proposed rule filing and order approving SCCP's restructured business, many SCCP rules were amended and discussed at length.[4] No new rule changes are proposed at this time. Thus, the purpose of the proposed rule change is to extend without change or modification the effectiveness of SCCP's restructured business.

SCCP believes the extension of the Commission's temporary approval to permit SCCP's continued operation of its restructured and limited clearance and settlement services is consistent with the requirements of the Act and the rules and regulations thereunder applicable to SCCP and in particular with Section 17A(b)(3)(F) which requires that a clearing agency be organized and its rules be designed, among other things, to promote the prompt and accurate clearance and settlement of securities transactions. SCCP believes that the extension of SCCP's restructured business should promote the prompt and accurate clearance and settlement of securities transactions by integrating and consolidating clearing services available to the industry.

(B) Self-Regulatory Organization's Statement on Burden on Competition

Similar to the original proposed rule change and subsequent renewals, SCCP does not believe that this extension should impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Section 17A(b)(3)(F) of the Act[5] requires that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions. Based on the information the Commission has to date, the Commission believes that SCCP's restructured operations have functioned satisfactorily to provide prompt and accurate clearance and settlement. During the upcoming temporary approval period, the Commission expects to review with SCCP in detail the functioning of SCCP's restructured operations.

SCCP has requested that the Commission find good cause for approving the proposed rule change prior to the thirtieth day after publication of the notice of filing. The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the publication of notice of the filing. Approving prior to the thirtieth day after publication of notice will allow SCCP to continue to offer its restructured clearing operations for another year without interruption when the current temporary order expires on December 31, 2000.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of SCCP.

All submissions should refer to the File No. SR–SCCP–00–05 and should be submitted by January 26, 2001.

It is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,[6] that the proposed rule change (File No. SR–SCCP–00–05) be and hereby is approved through December 31, 2001.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–315 Filed 1–4–01; 8:45 am]

BILLING CODE 8010–01–M

[3] Securities Exchange Act Release Nos. 40872 (December 31, 1998) [File Number SR–SCCP–98–05] and 42320 (January 6, 2000) [File Number SR–SCCP–99–04].

[4] *Supra* note 2.

[5] 15 U.S.C. 79q–1(b)(3)(F).

[6] 15 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

[Program Announcement No. SSA–OESP–01–2]

Program: Cooperative Agreements for Benefits Planning, Assistance, and Outreach Projects

AGENCY: Social Security Administration.

ACTION: Announcement of the availability of fiscal year 2001 cooperative agreement funds and second request for applications.

SUMMARY: The Social Security Administration (SSA) announces its intention to competitively award cooperative agreements to establish community-based benefits planning, assistance, and outreach projects in certain States and portions of States. The purpose of these projects is to disseminate accurate information to beneficiaries with disabilities (including transition-to-work aged youth) about work incentives programs and issues related to such programs, to enable them to make informed choices about work.

DATES: The closing date for receipt of cooperative agreement applications under this announcement is April 5, 2001.

Prospective applicants are also asked to submit, preferably by February 5, 2001, a fax, post card, or letter of intent that includes (1) the program announcement number (SSA–OESP–01–2) and title (Benefits Planning, Assistance, and Outreach Program); (2) the name of the agency or organization that is applying; and (3) the name, mailing address, email address,

telephone number, and fax number for the organization's contact person.

The notice of intent is not required, is not binding, and does not enter into the review process of a subsequent application. The purpose of the notice of intent is to allow SSA staff to estimate the number of independent reviewers needed and to avoid potential conflicts of interest in the review. The notice of intent should be faxed to (410) 966–1278; mailed to Social Security Administration, Office of Employment Support Programs, Division of Employment Policy, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401; or emailed to *TTWWIIA@ssa.gov.*

FOR FURTHER INFORMATION CONTACT: Send questions about this announcement to the following Internet email address: *TTWWIIA@ssa.gov.* When sending in a question, reference program announcement number SSA–OESP–01–2 and the date of this announcement. Questions and answers will be posted to http://www.ssa.gov/work on the Frequently Asked_Questions page of the web site. Questioners will not be identified when questions are posted on the web site.

Although the Internet is the preferred method of communication, applicants who have questions about the program content of the application may also contact: Cindy Barcelles, Program Analyst, or Natalie Funk, Team Leader, Social Security Administration, Office of Employment Support Programs, Division of Employment Policy, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401. The telephone number for Cindy Barcelles is (410) 966–2668; for Natalie Funk, (410) 965–0078. The fax number is (410) 966–1278.

To obtain an application kit, see the instructions under part VI, section A. Although the Internet is SSA's preferred method of communication, for information regarding the application package, you may also contact: Phyllis Y. Smith, Dave Allshouse, or Gary Stammer, Social Security Administration, Office of Acquisition and Grants, Grants Management Team, 1–E–4 Gwynn Oak Building, 1710 Gwynn Oak Avenue, Baltimore, Maryland 21207–5279. The telephone numbers are: Phyllis Y. Smith, (410) 965–9518, Dave Allshouse, (410) 965–9262, or Gary Stammer, (410) 965–9501. The fax numbers are (410) 966–9310 or 966–1261.

SUPPLEMENTARY INFORMATION: President Clinton signed the bill that became Public Law 106–170 on December 17, 1999 to expand the availability of health care coverage for working individuals with disabilities, to establish a Ticket to Work and Self-Sufficiency Program in SSA to provide beneficiaries with disabilities meaningful opportunities to work, and to provide benefits planning and assistance services, and outreach to beneficiaries with disabilities, among other purposes. SSA must ensure that benefits planning, assistance, and outreach are available to all beneficiaries with disabilities nationally, on a statewide basis.

On May 31, 2000, SSA made an announcement of cooperative agreement funds and requested applications at 65 FR 34768. SSA's intent is to establish benefits planning, assistance and outreach services in every State and U.S. Territory, and in the District of Columbia, and to ensure that services are available to all SSA beneficiaries with disabilities throughout each. Applications in response to our first announcement were not received from, or did not score highly enough in a review by independent panelists to be awarded for, the following locations:

- The entire States of Alabama, Nevada, North Dakota, Oregon, South Carolina, Tennessee, and Virginia; and
- Certain counties in the States of Florida, Georgia, Louisiana, and Minnesota. (See part II, section C, Number, Size, and Duration of Projects.)

This announcement is to request applications for fiscal year (FY) 2001 cooperative agreement funds to provide direct benefits planning, assistance and outreach services to all SSA disability beneficiaries in the locations listed above.

Note: SSA has awarded separate contracts to three organizations (Cornell University, Virginia Commonwealth University (VCU), and the University of Missouri-Columbia (UMO–C)) to develop and provide technical assistance and training on SSA's programs and work incentives, Medicare and Medicaid, and on other Federal work incentives programs, to Benefits Planning, Assistance, and Outreach Program cooperative agreement awardees. The contractors for projects targeting the following States are:

Minnesota: Cornell—Thomas P. Golden, *tpg3@cornell.edu,* (607) 255–2731;

Alabama, Florida, Georgia, Louisiana, Nevada, South Carolina, Tennessee, or Virginia: VCU—Susan O'Mara, (757) 412–2342; or Vicki Brooke, (804) 828–1873;

North Dakota or Oregon: UMO–C—C. David Roberts, robertsc@missouri.edu (program/project management), or Diana Beckley, *beckleyd@missouri.edu* (SSA/benefits planning technical knowledge): (573) 882–3807.

SSA will conduct pre-application seminars to provide interested applicants with guidance and technical assistance in preparing their applications. Information about where and when the seminars will be held will be on our web site: *www.ssa.gov/work/* Service Providers/Contracts and grants/BPAO.

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Part I. Program Description

A. Introduction

Section 1149 of the Social Security Act, as added by section 121 of the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA), requires the Commissioner of Social Security (the Commissioner) to establish a community-based work incentives planning and assistance program. Under this program, the Commissioner is required to establish a competitive program of grants, cooperative agreements, or contracts to provide benefits planning and assistance. We have established a cooperative agreement program known as the Benefits Planning, Assistance, and Outreach (BPAO) Program to disseminate accurate information to beneficiaries with disabilities about work incentives programs and issues related to such programs.

B. Background

Even though employment opportunities have increased due to technology, legislation, and changes in societal attitudes, only a small percentage of Social Security Disability Insurance (SSDI) and/or disabled or blind Supplemental Security Income (SSI) beneficiaries leave the rolls because of work activity. There are a number of reasons for this. First, beneficiaries of SSDI and SSI based on disability or blindness, by definition, have serious disabilities, which limit choices in employment. However, disability advocates report that many individuals with disabilities who receive public assistance want to work, or increase their work activity, and may be willing to attempt to work or increase work activity, with proper assistance and support. There is also evidence that many individuals with severe disabilities do work and do not rely on income supports.

Second, people with disabilities who want to work face significant barriers. Many advocates and people with disabilities contend that the fear of losing health care benefits is the largest impediment. Public health insurance and long-term care services are usually tied to income support programs such as SSDI, SSI, and Temporary Assistance for Needy Families (TANF). Employment-based health insurance is frequently not available to those with disabilities due to pre-existing condition clauses or exclusions of treatment for mental illness. Private insurance is often unaffordable for people with serious illnesses and chronic or long-term impairments, since they are charged much higher than average premiums.

Third, while the SSDI, SSI, Medicare and Medicaid programs all contain valuable work incentives provisions which can extend cash benefits and medical coverage, they are under-used and, often, are poorly understood by beneficiaries and professionals alike. The complexity and nature of the work incentives, and the interrelationship of myriad Federal, State, and local programs on which beneficiaries rely, create uncertainty and fear. Beneficiaries are concerned that they may lose vital income supports and coverage for mental and physical health care if they attempt to work.

For example, many people with disabilities rely on a patchwork of financial supports that have different eligibility criteria and application procedures. The benefits derived from a number of these programs are means-tested. Increases in income can also cause rent increases in section 8 housing, loss of food stamps or public assistance payments. Many individuals who may be willing to risk the loss of cash benefits from TANF, SSDI or SSI cannot absorb the loss of housing subsidies and other supports.

Despite these barriers, many people with severe disabilities have managed to use existing services and work incentives to reach their goals of financial self-sufficiency, while retaining necessary supports. However, those who are successful in returning to work frequently report that the availability of a knowledgeable advocate made a difference in their ability to navigate complex program requirements and in their willingness to attempt to return to work. Further, the support of that advocate provided them a sense of security needed to maintain work activity. The projects funded under this cooperative agreement program are part of SSA's Employment Strategy for People with Disabilities to increase the number of beneficiaries who return to work and achieve self-sufficiency by delivering direct services to beneficiaries.

C. Purpose of the Benefits Planning, Assistance, and Outreach Program

The purpose of the Benefits Planning, Assistance, and Outreach Program is to provide Statewide benefits planning and assistance, including information on the availability of protection and advocacy services, to all SSDI and SSI beneficiaries with disabilities, and to conduct ongoing outreach to those beneficiaries with disabilities (and to their families) who are potentially eligible to participate in State or Federal work incentives programs.

The Benefits Planning, Assistance, and Outreach Program is required by TWWIIA and is part of SSA's employment strategy for people with disabilities. One of SSA's goals in implementing TWWIIA is to help achieve a substantial increase in the number of beneficiaries who return to work and achieve self-sufficiency. In support of this goal, SSA is seeking well-qualified applicants to provide SSDI and SSI beneficiaries with benefits planning, assistance, and outreach. While other parts of SSA's employment strategy for people with disabilities provide direct employment services to help beneficiaries become employed or increase their level of employment, this program aims to improve beneficiaries' understanding of work options so that they may make more informed choices regarding work.

D. Benefits Planning, Assistance, and Outreach Program Goals

The goal of the Benefits Planning, Assistance, and Outreach Program is to support SSA's overall employment strategy for persons with disabilities by providing benefits planning and assistance, and conducting outreach to beneficiaries with disabilities, about Federal, State, and local work incentives programs and related issues.

To assist SSA in assessing the scope and utility of outreach and information provided under this program, each project will be required to:

1. collect data pertaining to benefits planning and assistance, and outreach activities as described in Part IV, Section D, Management Information and Reporting; and

2. cooperate with SSA in providing the information needed for a customer satisfaction survey on the quality of the benefits planning and assistance services being provided and for an assessment of the success of the Benefits Planning, Assistance, and Outreach Program.

Note: SSA plans to conduct such surveys in years two and five of the projects. More frequent surveys may be conducted if a need is indicated by the results of the first survey.

SSA will evaluate the data in 1. above and the results of the customer satisfaction surveys to determine the extent to which the projects were effective in providing benefits planning and assistance services, and outreach. The effectiveness of the projects will be measured by the range of beneficiaries served and responses regarding the knowledge of SSA work incentives and utility of benefits planning and assistance services. Data to be collected will include information about:

- Beneficiaries who receive comprehensive, coordinated benefits planning and assistance services, and outreach;
- Beneficiaries' demographic characteristics;
- Beneficiaries' income support characteristics (including earnings and SSA and non-SSA benefits);
- Beneficiaries' non-income support characteristics (including access to public and private health care); and
- Beneficiaries' work and benefit related goals and strategies.

Part II. Authority and Type of Awards

A. Statutory Authority and Catalog of Federal Domestic Assistance Number

Legislative authority for this cooperative agreement program is in section 1149 of the Social Security Act (the Act), as established by section 121 of the TWWIIA, Public Law 106–170.

The regulatory requirements that govern the administration of SSA awards are in the Code of Federal Regulations, title 45, parts 74 and 92. Applicants are urged to review the requirements in the applicable regulations. This program is listed in the Catalog of Federal Domestic Assistance under Program No. 96.008, Social Security Administration—Benefits Planning, Assistance, and Outreach Program.

B. Type of Awards

All awards made under this program will be in the form of cooperative agreements. A cooperative agreement anticipates substantial involvement between SSA and the awardee during the performance of the project. Involvement will include collaboration or participation by SSA in the management of the activity as determined at the time of the award. For example, SSA will be involved in decisions involving strategy, hiring of personnel, deployment of resources, release of public information materials, quality assurance, and coordination of activities with other offices.

C. Number, Size, and Duration of Projects

Section 1149(d) of the Act authorizes annual appropriations not to exceed $23 million for FYs 2000 through 2004. Actual funding availability during this period is subject to annual appropriation by Congress. If funds are available, SSA intends to fund a limited number of awards in FY 2001. SSA anticipates that all awards under this announcement will be made by April 30, 2001.

SSA will award a cooperative agreement to a qualified entity based in part on the number of beneficiaries with disabilities in the State where the project is located, with the following limitations:

- No entity shall receive a cooperative agreement for a fiscal year that is less than $50,000 or more than $300,000; and
- The total amount of all grants, cooperative agreements, or contracts awarded for the Benefits Planning, Assistance, and Outreach Program for any fiscal year (including amounts awarded for technical assistance and training contracts) may not exceed $23 million.

Within these limitations, SSA intends to establish as many projects as needed to ensure Statewide benefits planning, assistance, and outreach to all SSDI and SSI beneficiaries nationally. The applicant must demonstrate in sufficient detail that the number of beneficiaries with disabilities within the targeted area is sufficient to support a minimum award ($50,000), considering that SSA must ensure that all disability beneficiaries have access to benefits planning, assistance, and outreach.

Subject to the availability of funds, SSA anticipates that the following amounts per State would be available to fund all of the Benefits Planning, Assistance and Outreach Program projects in these States, in FY 2001:

- Alabama—$474,952*
- Nevada—101,872
- North Dakota—50,000
- Oregon—206,037
- South Carolina—375,854*
- Tennessee—562,173*
- Virginia—468,588*

***Note:** No entity may receive an award of more than $300,000.

Subject to the availability of funds, SSA anticipates that the following amounts would be available for projects targeting the following groups of counties in these States, in FY 2001:

- Florida

Charlotte, Collier, Desoto, Glades, Hardee, Hendry, Highlands, Lee and Okeechobee—$64,728

Alachua, Baker, Bay, Bradford, Brevard, Calhoun, Clay, Columbia, Dixie, Duval, Escambia, Flagler, Franklin, Gadsden, Gilchrist, Gulf, Hamilton, Holmes, Indian River, Jackson, Jefferson, Lafayette, Leon, Liberty, Madison, Marion, Nassau, Okaloosa, Putnam, St. Johns, Santa Rosa, Suwanne, Taylor, Union, Volusia, Wakulla, Walton, Washington—$329,619*

***Note:** No entity may receive an award of more than $300,000.

- Georgia

Appling, Atkinson, Bacon, Baker, Banks, Bartow, Ben Hill, Berrien, Brantley, Brooks, Bryan, Bulloch, Burke, Calhoun, Camden, Candler, Catoosa, Charlton, Chatham, Chattahootchee, Chattooga, Clay, Clinch, Coffee, Colquitt, Columbia, Cook, Coweta, Dade, Dawson, Decatur, Early, Echols, Effingham, Elbert, Emanuel, Evans, Fannin, Floyd, Franklin, Gilmer, Glascock, Glynn, Gordon, Grady, Greene, Habersham, Haralson, Harris, Hart, Heard, Irwin, Jackson, Jeff Davis, Jefferson, Jenkins, Johnson, Lamar, Lanier, Liberty, Lincoln, Long, Lowndes, Lumpkin, McDuffie, McIntosh, Madison, Marion, Meriwether, Miller, Mitchell, Montgomery, Murray, Muscogee, Oglethorpe, Pickens, Pierce, Pike, Polk, Quitman, Rabun, Randolph, Richmond, Schley, Screven, Seminole, Spalding, Stephens, Stewart, Sumter, Talbot, Taliaferro, Tattnall, Taylor, Telfair, Terrell, Thomas, Tift, Toombs, Towns, Treutlen, Troup, Turner, Union, Upson, Walker, Ware, Warren, Wayne, Webster, Wheeler, White, Whitfield, Wilcox, Wilkes, Worth—$313,908*

***Note:** No entity may receive an award of more than $300,000.

- Louisiana

Jefferson, Lafourche, Orleans, Plaquemines, St. Bernard, St. Charles, St. James, St. John the Baptist—$135,882

- Minnesota

Aitkin, Anoka, Becker, Beltrami, Benton, Big Stone, Brown, Carlton, Carver, Cass, Chippewa, Chisago, Clay, Clearwater, Cook, Cottonwood, Crow Wing, Douglas, Grant, Hennepin, Hubbard, Isanti, Itasca, Jackson, Kanabec, Kandiyohi, Kittson, Koochiching, Lac qui Parle, Lake, Lake of the Woods, Lincoln, Lyon, McLeod, Mahnomen, Marshall, Martin, Meeker, Mille Lacs, Morrison, Murray, Nicollet, Nobles, Norman, Otter Tail, Pennington, Pine, Pipestone, Polk, Pope, Ramsey, Red Lake, Redwood, Renville, Rock, Roseau, St. Louis, Sherburne, Sibley, Stearns, Stevens, Swift, Todd, Traverse, Wadens, Washington, Watonwan, Wilkin, Wright, Yellow Medicine—$214,635

SSA intends to enter into cooperative agreements during the 5-year authorization period subject to the availability of annual appropriations by Congress. SSA may suspend or terminate any cooperative agreement in whole or in part at any time before the date of expiration, whenever it determines that the awardee has materially failed to comply with the terms and conditions of the cooperative agreement. SSA will promptly notify the awardee in writing of the determination and the reasons for suspension or termination together with the effective date.

D. Awardee Share of the Project Costs

Awardees of SSA cooperative agreements are required to contribute a non-Federal match of at least 5 percent toward the cost of each project. The cost of the project is the sum of the Federal share (up to 95 percent) and the non-Federal share (at least 5 percent). For example, an entity that is awarded a cooperative agreement of $100,000 would need a non-Federal share of at least $5,263. The non-Federal share may be cash or in-kind (property or services) contributions.

Part III. The Application Process

A. Eligible Applicants

A cooperative agreement may be awarded to any State or local government, public or private organization, or nonprofit or for-profit organization that the Commissioner determines is qualified to provide benefits planning, assistance, and outreach to all SSDI and SSI beneficiaries with disabilities, within the targeted geographic area. Awardees may include Centers for Independent Living established under title VII of the Rehabilitation Act of 1973, protection and advocacy organizations, Native American tribal entities, client assistance programs established in accordance with section 112 of the Rehabilitation Act of 1973, State Developmental Disabilities Councils established in accordance with section 124 of the Developmental Disabilities Assistance and Bill of Rights Act, and State agencies administering the State program funded under part A of title IV of the Act. The Commissioner may also award a cooperative agreement to a State or local Workforce Investment Board, a Department of Labor (DOL) One-Stop Career Center System established under the Workforce Investment Act of 1998, or a State vocational rehabilitation agency.

SSA encourages applications from public or private agencies or organizations, including from local or divisional offices of larger or statewide agencies or organizations.

Applications from local or divisional offices of larger entities, however, must demonstrate that the local or divisional office has authority to enter into cooperative agreements and to be ultimately responsible for funds.

Note: For-profit organizations may apply with the understanding that no cooperative agreement funds may be profit to an awardee of a cooperative agreement. Profit is considered as any amount in excess of the allowable costs of the cooperative agreement awardee. A for-profit organization is a corporation or other legal entity that is organized or operated for the profit or benefit of its shareholders or other owners and must be distinguishable or legally separable from that of an individual acting on his/her own behalf. Applications will not be accepted from applicants which do not meet the above eligibility criteria at the time of submission of applications.

Cooperative agreements may not be awarded to:

- Any individual;
- Social Security Administration Field Offices;
- Any State agency administering the State Medicaid program under title XIX of the Act;
- Any entity that the Commissioner determines would have a conflict of interest if the entity were to receive a cooperative agreement under the Benefits Planning, Assistance, and Outreach Program; or
- Any organization described in section 501(c)(4) of the Internal Revenue Code of 1968 that engages in lobbying (in accordance with section 18 of the Lobbying Disclosure Act of 1995, 2 U.S.C. 1611).

Note: Any protection and advocacy organization must fully explain how it will ensure there will be no conflict of interest between providing benefits planning and assistance services and outreach, and delivering protection and advocacy services to beneficiaries. In particular, they must show how they will ensure full protection and advocacy services will be provided when the complaint is against the Benefits Specialist or organization. Also, any organization that will apply to be an employment network under SSA's Ticket to Work and Self-Sufficiency Program must fully explain how it will ensure there will be no conflict of interest if it also receives a cooperative agreement to provide benefits planning, assistance, and outreach. This is especially important in the area of assisting beneficiaries with PASS plans or other work incentives which will enable them to keep receiving benefits, thus delaying, or preventing entirely, payments to the employment network.

B. Targeted Geographic Area/ Population

To ensure statewide availability of benefits planning, assistance, and outreach, as required by section 1149 of the Act, SSA intends to award cooperative agreements partly on the basis of geographic area.

While SSA recognizes that not every SSDI or SSI beneficiary with a disability will access benefits planning, assistance, and outreach, it must be available to each via the project targeting a specific geographic area. Therefore, each awarded project must make those services available to all SSDI and SSI beneficiaries with disabilities within the geographic area it serves. Because youth with disabilities is such an important population to target for those services, each project must make benefits planning, assistance, and outreach available to SSI recipients as young as age 14. In providing benefits planning, assistance, and outreach, projects must make concerted and aggressive efforts to address the needs of underserved individuals with disabilities from diverse ethnic and racial communities (*e.g.,* Native Americans, Vietnamese). In particular, applicants should show how they intend to do outreach in ways that ensure interaction with diverse communities and must specify the geographic area they wish to cover.

Entities are encouraged to collaborate with other public and/or private organizations (*e.g.,* DOL One-Stop Career Center), through interagency agreements or other mechanisms, if necessary, to integrate services to beneficiaries with disabilities. Entities should also consider collaboration with other organizations to prepare an application for a cooperative agreement to provide benefits planning, assistance, and outreach to all beneficiaries within a specific area. For example, Native American tribal governments may collaborate to develop a proposal to cover specified reservation lands.

All applications developed jointly by more than one agency or organization must identify only one organization as the lead organization and official applicant. The other participating agencies and organizations can be included as co-applicants, subgrantees or subcontractors. However, where more than the maximum award amount is requested, and would be awarded for the targeted geographic area, collaborating agencies should submit separate applications.

C. Application Process

The cooperative agreement application process consists of a one-stage, full application. Independent reviewers will competitively review the application against the evaluation criteria specified in this announcement (see Part V). Applications will be reviewed against others targeting the same State or locality; for example, an application targeting the State of Alabama will be competitively reviewed against all other applications targeting Alabama, including any that might target both Georgia and Alabama, or only specific portions of Alabama. (SSA must ensure that all beneficiaries with disabilities have access to benefits planning, assistance, and outreach throughout each of the States.)

D. Application Consideration

Applications will be initially screened for relevance to this announcement. If judged irrelevant, the application will be returned to the applicant. Also, applications that do not meet the applicant eligibility criteria in Section A above will not be accepted.

Applications that are complete and conform to the requirements of this announcement, the instructions in Form SSA–96–BK, and the separate instructions for completing Part III, Program Narrative (of the SSA–96–BK), will be reviewed competitively against the evaluation criteria specified in Part

V of this announcement and evaluated by Federal and non-Federal personnel. See part VI for instructions on obtaining Form SSA–96–BK. The results of this review and evaluation will assist the Commissioner in making award decisions. Although the results of this review are a primary factor considered in making the decisions, the review score is not the only factor used. In selecting eligible applicants to be funded, consideration will be given to achieving statewide accessibility to benefits planning, assistance, and outreach to avoiding unnecessary duplication of effort.

The application requirements in part IV are the minimum amount of required project information. Projects are responsible for collecting management information (MI) according to the guidelines provided, producing regular reports according to the guidelines provided, and producing a final report which analyzes the successes and/or failures of the methodology used to provide benefits planning, assistance, and outreach to SSDI and SSI beneficiaries, and others.

All projects must adhere to SSA's Privacy and Confidentiality Regulations (20 CFR part 401) for maintaining records of individuals, as well as provide specific safeguards surrounding beneficiary information sharing, paper/computer records/data, and other issues potentially arising from providing benefits planning, assistance, and outreach to SSDI and SSI beneficiaries with disabilities.

E. Application Approval

Cooperative agreement awards will be issued within the constraints of available Federal funds and at the discretion of SSA. The official award document is the ''Notice of Cooperative Agreement Award.'' It will provide the amount of the award, the purpose of the award, the term of the agreement, the total project period for which support is contemplated, the amount of financial participation required, and any special terms and conditions of the cooperative agreement.

F. Costs

Federal cooperative agreement funds may be used for allowable costs incurred by awardees in conducting direct benefits planning, assistance, and outreach services to SSA's beneficiaries with disabilities. These costs could include administrative and overall project management costs, within the limitations discussed earlier.

Federal cooperative agreement funds are not intended to cover costs that are reimbursable under an existing public or private program, such as social services, rehabilitation services, or education. No SSDI or SSI beneficiary can be charged for any service delivered under a Benefits Planning, Assistance, and Outreach Program cooperative agreement, including preparing a PASS. Benefits planning and assistance services are intended to be free and must be made accessible to all SSA beneficiaries with disabilities in the project's target geographical area. Project funds should not be used to create new benefits or extensions of existing benefits.

Part IV. Program Requirements

A. General Requirements

The cooperative agreement awardees shall:

1. Provide the location of the targeted service area(s) (by county, and independent city in VA) to SSA as part of the application (see Part III, Section B, Targeted Geographic Area/Population);

2. Work with SSA's technical assistance and training contractor in arranging training for Benefits Specialists;

3. Provide a brief project description to the contractor;

4. Employ Benefits Specialists and have them attend an initial 5-day face-to-face training session within 90 days of award of the cooperative agreement. SSA's technical assistance and training contractor will provide technical assistance and training to projects about SSA's programs and work incentives (*e.g.,* trial-work period (TWP), extended period of eligibility (EPE), impairment-related work expenses (IRWE), Plan for Achieving Self-Support (PASS), 1619(a) and (b), and Medicaid buy-in provisions/Balanced Budget Act); Medicare and Medicaid; and on other Federal work incentives programs. (SSA will attend that training session to provide a half-day orientation session for project directors.) The applicant is responsible for providing technical assistance and training to Benefits Specialists about State and local programs.

5. Have Benefits Specialists attend refresher/follow-up and new hire training sessions, as needed, and take part in the evaluation of training activities and the evaluation of ongoing training needs evaluation by the contractor.

6. Within 90 days after award, the applicant will ensure Benefits Specialists have completed training, have developed outreach plans and begun initial outreach, and are prepared to provide direct benefits planning and assistance services to all SSDI and SSI beneficiaries with disabilities within the targeted geographic area who are requesting these services;

7. Finalize the MI system data collection elements (as defined by SSA) and procedures with SSA within 60 days after award;

8. Develop and submit quarterly reports that contain MI to SSA, Office of Acquisition and Grants (OAG);

9. Develop and submit quarterly financial reports to SSA, OAG;

10. Provide a description of all planned changes to the project design for approval by SSA prior to implementation;

11. Cooperate with SSA in scheduling and conducting site visits;

12. Develop and maintain a collaborative working relationship with the local servicing Social Security office;

13. Implement an ongoing management and quality assurance process that uses MI data; and

14. Attend scheduled conferences, participate in panel and small group discussions, and make project presentations.

B. Description of Projects

The project awardees shall:

- Provide direct individualized benefits planning and assistance, including information on the availability of protection and advocacy services, to beneficiaries with disabilities, including individuals participating in the Ticket to Work and Self-Sufficiency Program established under section 1148 of the Act, the program established under section 1619 of the Act, and other programs that are designed to encourage disabled beneficiaries to work;
- Conduct ongoing outreach efforts to beneficiaries with disabilities (and to the families of such beneficiaries) who are potentially eligible to participate in Federal or State work incentives programs that are designed to assist beneficiaries with disabilities to work, by preparing and disseminating information and explaining such programs. In conducting benefits planning, assistance, and outreach activities, project awardees will work in cooperation with other Federal, State, and private agencies and nonprofit organizations that serve beneficiaries with disabilities, and with agencies and organizations that focus on vocational rehabilitation and work-related training and counseling, including DOL One-Stop Career Centers.

In order to be considered for an award, applicants must describe:

• Their understanding of benefits planning and assistance, including the benefits programs with which they have worked in the past;

• How they will notify all SSDI and SSI beneficiaries with disabilities in the targeted geographic area about benefits planning and assistance and provide those services to beneficiaries;

• Their understanding of outreach, and how they will conduct outreach to all SSDI and SSI beneficiaries with disabilities (and their families) in the targeted geographic area who are potentially eligible to participate in Federal or State work incentives programs designed to assist beneficiaries with disabilities to work, and, particularly, how the outreach strategies, information, and materials will be modified to seek out different ethnic and racial groups;

• The scope of the project; and

• How that project achieves the Benefits Planning, Assistance, and Outreach Program goals in Part I, Section D.

The applicants must also describe how they will address any special cultural requirements of populations (*e.g.,* Native Americans) within the targeted geographic area, as well as non-English speaking populations (*e.g.,* Vietnamese) and SSI recipients as young as age 14.

In providing benefits planning and assistance services, and conducting outreach, projects must be sensitive to issues such as cultural differences and non-English speaking populations within the areas they serve (*e.g.,* Native Americans, Vietnamese). Specifically, projects must address the needs of underserved individuals with disabilities from diverse ethnic and racial communities and show how they intend to provide outreach in ways that ensure interaction with diverse communities.

Applicants must also provide information on:

• Collaborative relationships with relevant agencies, including SSA's field offices, and organizations (*e.g.,* Centers for Independent Living, DOL One-Stop Career Centers);

• Specific services and supports that will be involved in the project and their roles;

• Case management and monitoring systems and techniques to be used;

• Methods of evaluating benefits planning, assistance, and outreach provided; and

• The MI and quality assurance process that will be used.

Applicants must also describe how Benefits Specialists will be trained on numerous supports which are often used by people with disabilities, such as long-term care, subsidized housing, paratransit, and food stamps; variations in benefits and services in the State in which the applicant is located; the State's work incentives programs; workers' compensation and unemployment insurance programs; vocational rehabilitation services; work-related training and counseling programs; and other community-based support programs designed to enable people with disabilities to work.

Applicants must also describe how Benefits Specialists will be trained to conduct outreach by providing information, guidance, and planning to beneficiaries with disabilities on the:

• Availability and interrelation of any Federal or State work incentives programs designed to assist beneficiaries with disabilities for which the individual may be eligible to participate;

• Adequacy of any health benefits coverage that may be offered by an employer of the individual and the extent to which other health benefits coverage may be available to the individual; and

• Availability of protection and advocacy services for beneficiaries with disabilities and how to access such services.

Note: The technical assistance and training contractor may provide technical assistance materials to enable project Benefits Specialists to get information about the subjects in the preceding paragraphs. However, each awardee shall be responsible for ensuring that Benefits Specialists are well-versed in these areas.

Applicants must describe any plans they have to collaborate or coordinate with public and private organizations to achieve and/or improve their project goals and submit evidence to SSA of these organizations' capabilities, and willingness to participate (*e.g.,* letters of intent, memoranda of understanding). Applicants should not request letters of intent or commitment from SSA field offices. SSA will assure field office cooperation.

Each applicant must describe the number of beneficiaries with disabilities it expects to serve. If the target group is not large enough to justify a minimum award of $50,000, the applicant will not be considered further.

Note: All SSDI and SSI beneficiaries (including SSI recipients as young as age 14) within the geographic area served by the project, must be able to access benefits planning, assistance, and outreach via the project.

The project may be part of a larger State initiative; *e.g.,* a DOL One-Stop Career Center, that serves other individuals with disabilities, such as TANF recipients; however, funds provided by SSA under the cooperative agreements cannot be used to serve people with disabilities who are not beneficiaries of SSDI and/or SSI.

C. Benefits Specialist Responsibilities and Competencies

1. Responsibilities

Cooperative agreement awardees shall select individuals who will act as Benefits Specialists. Benefits Specialists will provide work incentives planning and assistance directly to beneficiaries with disabilities; conduct outreach efforts to beneficiaries with disabilities (and their families), who are potentially eligible to participate in Federal or State work incentives programs designed to assist disabled beneficiaries to work; and work in cooperation with Federal, State, and private agencies and nonprofit organizations that serve beneficiaries with disabilities. Benefits Specialists will also provide information on the adequacy of health benefits coverage that may be offered by an employer of a beneficiary with a disability; the extent to which other health benefits coverage may be available to that beneficiary; and the availability of protection and advocacy services for beneficiaries with disabilities, and how to access such services.

Benefits Planning

Benefits planning requires an in-depth understanding of the current status of a beneficiary being served. Initial benefits planning will support a beneficiary over a period of several weeks to several months, concluding when the beneficiary has received guidance to support informed choices. Benefits Specialists will establish plans for beneficiaries with disabilities, and develop long-term supports that may be needed to ensure success. Following the initial benefits planning process, they will provide periodic, follow-up planning services to ensure that the information, analysis, and guidance are updated as new conditions (with regard to the applicable programs or to the individual's situation) arise.

To provide benefits planning services, Benefits Specialists will:

• Obtain and evaluate comprehensive information about a beneficiary with a disability, on the following:

—Beneficiary background information,
—Disability,
—Employment and earnings,
—Resources,
—Federal and State benefits,
—Health insurance,

—Work expenses,
—Work incentives, and
—Service(s) and supports;

• Assess the potential impacts of employment and/or other changes on a beneficiary's Federal and State benefits eligibility and overall financial well-being;

• Provide information and assist the beneficiary in understanding and assessing the potential impacts of employment and/or other actions or changes on his/her life situation, and provide specific guidance regarding the affects of various work incentives;

• Develop a comprehensive framework of possible options available to a beneficiary and projected results for each as part of the career development and employment process; and

• Ensure confidentiality of all information provided.

Benefits Assistance

Benefits assistance involves the delivery of information and direct supports for the purpose of assisting a beneficiary in dealing with benefit issues and effectively managing benefits. Benefits assistance also involves providing information and referral and problem-solving services as needed. Benefits management services will generally build on previous planning and assistance services and include periodic updates of an individual's specific information, reassessment of benefit(s) and overall impacts, education and advisement, and additional planning for monitoring and managing benefits and work incentives.

To provide benefits assistance services, Benefits Specialists will:

• Provide time-limited direct assistance to a beneficiary in the development of a comprehensive, long-term benefits management plan to guide the effective monitoring and management of Federal and State benefits and work incentives. Specific components of the plan must address:
—Desired benefit and work outcomes,
—Related steps or activities necessary to achieve outcomes,
—Associated dates or time frames,
—Building on initial benefits planning efforts including information gathering, analysis and advisement, and
—Benefits/financial analysis (pre- and post-employment);

• Provide time-limited, intensive assistance to beneficiaries, their key stakeholders, and their support teams in making informed choices and establishing both employment-related goals as well as needed benefits management supports. Needed benefits assistance could include:
—How SSDI and SSI work incentives programs may lead to self-supporting employment by developing a PASS,
—Developing a PASS which can be used to obtain training, education, and entrepreneurial opportunities,
—How a PASS can be used to address some of the barriers to employment, such as obtaining a car for transportation needs, and
—The 1619(b) provisions and requirements;

• Advocate on behalf of a beneficiary with other agencies and programs, which requires in-person, telephone and/or written communication with the individual and other involved parties generally over a period of several weeks to several months;

• Provide time-limited follow-up assistance as needed to beneficiaries who have previously received benefits planning and/or other types of benefits assistance services and:
—Assist them and other involved parties to update information,
—Reassess impact of employment and other changes on benefits and work incentives, and
—Provide additional guidance on benefit options, issues and management strategies;

• Assist beneficiaries as needed to update benefits management plan;

• Provide information, referral, and problem-solving support;

• Provide ongoing, comprehensive, benefits monitoring and management assistance to beneficiaries who are likely to experience employment, benefits, or other changes that may dramatically affect their benefit(s) status, health care, or overall financial well being; and

• Provide long-term benefits management on a scheduled, continuous basis, allowing for the planning and provision of supports at regular checkpoints, as well as critical transition points in an individual's benefits, employment and overall situation.

Outreach

Outreach activities are ongoing, systematic efforts to inform individuals of available work incentives, as well as the services and supports available to enable them to access and benefit from those work incentives. Outreach efforts should be targeted directly to SSDI and SSI beneficiaries with disabilities, their families, and to advocacy groups and service provider agencies that have regular contact with them. Outreach activities should be directed toward and sensitive to the needs of individuals from diverse ethnic backgrounds, persons with English as their second language, as well as non-English speaking persons, individuals residing in highly urban or rural areas, and other traditionally underserved groups.

To conduct ongoing outreach, Benefits Specialists will:

• Prepare and disseminate information explaining Federal or State work incentives programs and their interrelationships; and

• Work in cooperation with other Federal, State, and private agencies and nonprofit organizations that serve beneficiaries with disabilities, and with agencies and organizations that focus on vocational rehabilitation and work-related training and counseling.

The Benefits Specialists will conduct outreach to SSDI and SSI beneficiaries with disabilities (and their families), who are potentially eligible to participate in Federal or State work incentives programs that are designed to assist beneficiaries with disabilities to work.

2. Competencies

Applicants must ensure that Benefits Specialists have the skills required to competently provide benefits planning and assistance services, and outreach. We prefer that cooperative agreement awardees use Benefits Specialists who have attained a bachelor's degree in a relevant field, or that they use Benefit Specialists with relevant experience. Benefit Specialists may possess a combination of education and experience if the experience provides the knowledge, skills and abilities to successfully perform the duties of the position.

Benefits Specialists should bring the following knowledge, skills, and abilities to the position:

• Basic math skills, with an emphasis on problem solving;

• Deductive ability with analytical thinking and creative problem solving skills;

• Acceptable interviewing skills;

• Ability to interpret Federal laws, regulations, and administrative code about public benefits;

• Communication skills (written and/or verbal);

• Knowledge of medical terminology and awareness of cultural and political issues pertaining to various populations and to various disabilities; and

• Basic computer skills.

Benefits Specialists will need to become proficient in the following knowledge, skills, and abilities:

• SSDI and SSI disability programs;

• Knowledge of all public benefits programs, including operations and inter-relationships;

- Translating technical information for lay individuals;
- Accessing information in a variety of ways (including the ability to be able to recognize when additional information is needed);
- Interpersonal skills (*e.g.,* recognize and help people manage anger and conflict, enjoy working with individuals);
- Counseling skills (ability to listen, evaluate alternatives, advise on potential cause of action);
- Knowledge of SSA field office structure and how to work with various work incentives coordinators (*e.g.,* PASS specialists, employment support representatives);
- Knowledge of the structure and design of public and private benefits systems and local community services; and
- Knowledge of ethics (*e.g.,* confidentiality, conflict of interest).

The applicant must clearly explain how it will ensure all individuals hired as Benefits Specialists will possess or acquire the relevant knowledge, skills and abilities. SSA has contracted with separate entities to provide technical assistance and training to cooperative agreement awardees on an ongoing basis about SSA's programs and work incentives, Medicare and Medicaid, and other Federal work incentives programs. Those entities are: Cornell University for SSA Regions I, II and V (which includes Minnesota); Virginia Commonwealth University for Regions III (including Virginia), IV (including Alabama, Florida, Georgia, South Carolina, and Tennessee), VI (including Louisiana), and IX (including Nevada); and the University of Missouri, Columbia for Regions VII, VIII (including North Dakota), and X (including Oregon). The applicant is responsible for providing technical assistance and training to Benefits Specialists about State and local programs.

D. Management Information and Reporting

In addition to cooperating with the surveys outlined in Part I, Section D, entities must provide all collected data and report the results to SSA's Office of Acquisition and Grants, as described below.

Common data elements, as defined by SSA, will be collected by all projects. The awardee and SSA will use the management information (MI) data to manage the project and to determine what additional resources or other approaches may be needed to improve the process. The data will also be valuable to SSA in its analysis of and future planning for the SSDI and SSI programs.

All projects must adhere to SSA's Privacy and Confidentiality Regulations (20 CFR part 401) for maintaining records of individuals, as well as provide specific safeguards surrounding beneficiary information sharing, paper/computer records/data, and other issues potentially arising from providing benefits planning, assistance, and outreach to SSDI and SSI beneficiaries with disabilities.

All projects shall provide for the design, development, implementation, and maintenance of an MI system, which must be compatible with SSA database specifications that are fixed-format ASCII files. The MI system shall allow for necessary data collection on SSDI and SSI beneficiaries. For the purpose of providing MI to SSA in support of the implementation and management of the projects, projects will collect, analyze, and summarize the data listed below:

Beneficiary Background Information

1. Beneficiary/recipient name (Last, First, Middle)
2. Date of birth
3. Gender
4. Special language or other considerations
5. Mailing address
6. Telephone number
7. Social Security number
8. Representative payee (RP) name (if applicable)
9. RP address
10. Current level of education
11. Whether pursuing education currently and at what level (*e.g.,* post secondary, continuing adult education, special education, vocational education)
12. Proposed educational goals
13. Primary diagnosis
14. Secondary diagnosis (if applicable)
15. Employer health care coverage at outset (if working)
16. Other health care coverage

Employment Information (current and proposed goal—where applicable)

1. Self-employed or employee
2. Type of work
3. Beginning date
4. Hours per week
5. Monthly gross earned income
6. Monthly net earned income
7. Work-related expenses

Proposed Training Information

1. Work-related training/counseling program
2. Proposed other training

Benefits (current and expected changes if employment goals are reached)

1. SSDI
2. SSI
3. Concurrent (SSDI and SSI)
4. Medicare
5. Medicaid
6. Subsidized housing or other rental subsidies
7. Food Stamps
8. General Assistance
9. Workers Compensation benefits
10. Unemployment Insurance benefits
11. Other Federal, State, or local supports, including TANF (specify)

Incentives To Be Used

1. Trial-work period (TWP)
2. Extended period of eligibility (EPE)
3. Impairment-related work expenses (IRWE)
4. Plan for achieving self-support (PASS)
5. 1619(a)
6. 1619(b)
7. Medicaid buy-in provisions/Balanced Budget Act

Services To Be Used

1. Vocational Rehabilitation services
2. Paratransit services
3. Protection and Advocacy services
4. Work-related training/counseling program
5. DOL One-Stop Career Center services
6. Transitioning youth services (from school to post-secondary education or to work)

Monthly Benefits Planning, Assistance, and Outreach Activities Performed by Benefits Planning Organization

1. Number of SSDI/SSI beneficiaries (over age 18) requesting assistance (initial and repeat requests)
2. Number of SSDI/SSI beneficiaries (ages 14 to 18) requesting assistance (initial and repeat requests)
3. Number of new benefits management plans prepared
4. Number of updated benefits management plans prepared
5. Number of presentations given at forums, conferences, meetings, etc.

All data elements are to be collected in accordance with precise definitions to be provided by SSA during start-up activities. Adherence to such precise definitions is crucial to the comparability of the data across project sites.

Entities awarded cooperative agreements under this notice shall submit quarterly progress reports to SSA, OAG. SSA expects that the projects will need a period of time to begin providing services and collecting management information. Therefore, the first quarterly report shall include a description of the project, a status of data collection operations, actions that were taken, planned actions, and a

description of how the project is addressing the needs of individuals with disabilities from diverse ethnic and racial communities, both in benefits planning and in carrying out outreach activities.

Subsequent reports shall provide: a status of the project, any problems or proposed changes in the project (*e.g.,* requests for technical assistance from contractor, interagency agreement change); specific information (baseline data/program statistics) required by SSA, including that listed above; a description of how the project is addressing the needs of individuals with disabilities from diverse ethnic and racial communities, both in benefits planning and in carrying out outreach activities; actions that were taken, and planned actions. The quarterly reports shall be submitted to SSA, OAG, within 30 days after the end of the quarter.

SSA personnel (SSA Project Officer and/or other staff) expect to visit each project at least once in each year of the cooperative agreement. The SSA Project Officer shall review site operations, including collection of management information, and evaluate how projects are finding ways to make benefits planning, assistance, and outreach activities more effective in achieving SSA's Benefits Planning, Assistance, and Outreach Program goals.

Staff members from each project shall attend an initial training meeting that will include an orientation session by SSA, and subsequent scheduled conferences at SSA headquarters or alternate sites chosen by SSA. Those meetings will provide awardees of cooperative agreements with the opportunity to exchange information with SSA and other awardees.

E. Evaluation

Process Evaluation

The purpose of process evaluation is for SSA and the awardee to assess how the project functioned and how the process might be altered to more efficiently and/or successfully provide the services required under section 1149 of the Act. The process evaluation will require both data collection and qualitative observational evaluation through site visits and/or project reporting.

Participant Experience

The goal of these cooperative agreements is the provision of services to enhance beneficiary awareness and understanding of SSA work incentives and thereby enhance beneficiaries' ability to make informed choices regarding work. The goal is not to provide employment services. Nevertheless, SSA is clearly interested in identifying participant outcomes under the Benefits Planning, Assistance, and Outreach Program to determine the extent to which participants achieve their employment, financial, and health care goals. Therefore, SSA is requiring that cooperative agreement awardees collect data regarding the employment status, benefit status, and income of beneficiaries before providing services under these cooperative agreements. SSA intends to use this information to support the sample selection for participants in the customer satisfaction survey. This will allow SSA to include the experiences and outcomes of a broad range of beneficiaries.

Each project shall submit periodic reports (as described in Part IV, Section D, Management Information and Reporting) to SSA, OAG. Data and information that are used in preparing the reports can be used, for example, to improve the efficiency of the project's operations, use of staff, and linkages between the project and the programs for which benefits planning is needed to better meet the needs of target populations. In addition, the evaluation results will be disseminated to other projects to promote learning, program refinements, and facilitate partnership and achievement of project objectives. Timely comprehensive MI data also allows for cost accounting, which helps improve the efficiency of service approaches and may inform future policy decisions.

Part V. Application Review Process and Evaluation Criteria

A. Screening Requirements

All applications that meet the deadline will be screened to determine completeness and conformity to the requirements of this announcement. Complete and conforming applications will then be evaluated.

1. Number of Copies: The applicant must submit one original signed and dated application and a minimum of two copies. The submission of seven additional copies is optional and will expedite processing, but will not affect the evaluation or scoring of the application.

2. Length: The program narrative portion of the application (Part III of the SSA–96–BK) may not exceed 30 double-spaced pages (or 15 single-spaced pages) on one side of the paper only, using standard (8½″ x 11″) size paper, and 12-point font. Attachments that support the program narrative count towards the 30-page limit.

B. Evaluation Criteria

Applications that pass the screening process will be independently reviewed by at least three individuals, who will evaluate and score the applications based on the evaluation criteria. There are four categories of criteria used to score applications: capability; relevance/adequacy of program design; resources and management; and quality assurance plan. The total points possible for an application is 100, and sections are weighted as noted in the descriptions of criteria below.

Although the results from the independent panel reviews are the primary factor used in making funding decisions, they are not the sole basis for making awards. The Commissioner will consider other factors as well when making funding decisions. For instance, the need to assure the required geographic distribution of projects may take precedence over rankings/scores of the review panel.

Following are the evaluation criteria that SSA will use in reviewing all applications (relative weights are shown in parentheses):

1. Capability (20 points)

The applicant's capability to deliver benefits planning and assistance services will be judged by:

- Description of how entity will test for Benefits Specialist competencies listed in Part IV and provide any needed training to ensure competencies will be maintained and/or enhanced; (8 points)
- Description of the proposed administration and organization of the project, including the existence of the necessary administrative resources to effectively carry out the project; and (7 points)
- Project Director's and key staff's documentation of experience and results of past projects of this nature (extra consideration may be given to applicants based on the quality and extent of their experience in return-to-work efforts for SSDI and SSI beneficiaries with disabilities). (5 points)

2. Relevance/Adequacy of Project Design (30 points)

The adequacy of project design will be judged by:

- A description of the project operations, including how the project will work (*e.g.,* identification and notification of potential project participants about availability of benefits planning and assistance services, location for providing services, ability to travel to beneficiary, etc.) and

the quality of the project design; (6 points)

• A description of how the project will address provision of benefits planning, assistance, and outreach to transition-to-work aged SSI youth; (5 points)

• A description of how the project will address provision of benefits planning, assistance, and outreach to populations with special cultural or language requirements; (5 points)

• Evidence of collaboration with relevant agencies, including collocation within a DOL One-Stop Career Center organization, in providing benefits planning and assistance services; and extent and clarity of collaborative efforts with other organizations, including letters of intent or written assurances; and (5 points)

• A concise and clear statement of the project goals and objectives; MI data to be collected; specification of data sources; and how quality assurance will be realized; (4 points)

• Description of problems that may arise and how they will be resolved; *e.g.,* how dropouts and inadequate numbers of participants will be handled; and (3 points)

• Evidence of how the approach proposed will accomplish Benefits Planning, Assistance, and Outreach Program goals. (2 points)

3. Resources and Management (30 points)

Resources and management will be judged by:

• Appropriateness of qualifications of the project personnel, as evidenced by training and experience indicating that they have the skills required to competently provide benefits planning and assistance services, and outreach; (8 points)

• Evidence of successful previous experience related to benefits planning, assistance, and outreach programs; (4 points)

• Evidence that the applicant has a working knowledge of work incentives and the various programs available to beneficiaries with disabilities; (4 points)

• Evidence of adequate facilities (*e.g.,* collocation within a DOL One-Stop Career Center) and resources to deliver services; (4 points)

• Appropriateness of the case management and monitoring systems and techniques, including an MI system, quality assurance system, and a range of other monitoring and management options; (3 points)

• Extent and quality of project assurances that sufficient resources (including personnel, time, funds, and facilities) will be available to support services to beneficiaries; (3 points)

• Evidence that the applicant will meaningfully involve family members and other representatives of target groups, including advocates in the process of delivery services; and (2 points)

• Cost effectiveness, per client costs, and reasonableness of overall project cost relative to planned services. (2 points)

4. Quality Assurance (20 points)

The applicant's quality assurance plan will be judged by:

• Extent to which training is accommodated and planned for to ensure that all Benefits Specialists maintain knowledge, skills, and abilities, and acquire more; (6 points)

• Extent to which the awardee proposes to use MI data to improve processes and ensure that all information given is accurate and pertinent; (4 points)

• Extent to which the proposed quality assurance plan complies with the requirements of SSA, in terms of data collection, reporting, and ensuring that only accurate information is provided to beneficiaries and others; (4 points)

• Extent to which the proposed staff demonstrate expertise in the area of benefits planning and assistance; and (4 points)

• The extent to which staff have experience collecting, protecting, and analyzing data on beneficiaries with disabilities to provide benefits planning and assistance services, and outreach. (2 points)

Part VI. Instructions for Obtaining and Submitting Application

A. Availability of Forms

The Internet is the primary means recommended for obtaining an application kit under this program announcement. An application kit containing all of the prescribed forms and instructions needed to apply for a cooperative agreement under this announcement may be obtained at the following Internet address: *http//www.ssa.gov/oag/grants.*

Although the Internet is SSA's preferred method of making application kits available, an application kit also may be obtained by writing to: Grants Management Team, Office of Operations Contracts and Grants, OAG, Social Security Administration, 1–E–4 Gwynn Oak Building, 1710 Gwynn Oak Avenue, Baltimore, Maryland 21207–5279.

Requests submitted by mail should include two return address labels. Also, please provide the name, title and telephone number of the individual to contact; and the organization's name, street address, city, State and zip code.

To ensure receipt of the proper kit, please include program announcement number SSA–OESP–01–2 and the date of this announcement.

B. Checklist for a Complete Application

The checklist below is a guide to ensure that the application package has been properly prepared.

—An original, signed and dated application plus at least two copies. Seven additional copies are optional but will expedite processing.

—The program narrative portion of the application (Part III of the SSA–96–BK) may not exceed thirty double-spaced pages (or fifteen single-spaced pages) on one side of the paper only, using standard (8½″ x 11″) size paper, and 12-point font. Attachments that support the program narrative count towards the 30–page limit.

—Attachments/Appendices, when included, should be used only to provide supporting documentation. Please do not include books or videotapes as they are not easily reproduced and are therefore inaccessible to reviewers.

—A complete application, which consists of the following items in this order:

(1) Part I (Face page)—Application for Federal Assistance (SF 424, REV 4–88);

(2) Table of Contents;

(3) Project Summary (not to exceed one page);

(4) Part II—Budget Information, Sections A through G (Form SSA–96–BK);

(5) Budget Justification (in Section B Budget Categories, explain how amounts were computed), including subcontract organization budgets;

(6) Part III—Application Narrative and Appendices;

(7) Part IV—Assurances;

(8) Additional Assurances and Certifications—regarding Lobbying and regarding Drug-Free Workplace; and

(9) Form SSA–3966–PC—acknowledgement of receipt of application (applicant's return address must be inserted on the form).

C. Guidelines for Application Submission

All applications for cooperative agreement projects under this announcement must be submitted on the prescribed forms included in the application kit. The application shall be executed by an individual authorized to act for the applicant organization and to

assume for the applicant organization the obligations imposed by the terms and conditions of the cooperative agreement award.

In item 11 of the Face Sheet (SF 424), the applicant must clearly indicate the application submitted is in response to this announcement (SSA–OESP–01–2). The applicant also is encouraged to select a SHORT descriptive project title.

Applications must be mailed or hand-delivered to: Grants Management Team, Office of Operations Contracts and Grants, OAG, DCFAM, Social Security Administration, Attention: SSA–OESP–00–2, 1–E–4 Gwynn Oak Building, 1710 Gwynn Oak Avenue, Baltimore, MD 21207–5279.

Hand-delivered applications are accepted between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday. An application will be considered as meeting the deadline if it is either:

1. Received on or before the deadline date at the above address; or

2. Mailed through the U.S. Postal Service or sent by commercial carrier on or before the deadline date and received in time to be considered during the competitive review and evaluation process. Packages must be postmarked by April 5, 2001. Applicants are cautioned to request a legibly dated U.S. Postal Service postmark or to obtain a legibly dated receipt from a commercial carrier as evidence of timely mailing. Private-metered postmarks are not acceptable as proof of timely mailing.

Applications that do not meet the above criteria are considered late applications. SSA will not waive or extend the deadline for any application unless the deadline is waived or extended for all applications. SSA will notify each late applicant that its application will not be considered.

Paperwork Reduction Act

This notice contains reporting requirements. However, the information is collected using form SSA–96–BK, Federal Assistance Application, which has the Office of Management and Budget clearance number 0960–0184.

Dated: December 22, 2000.

Kenneth S. Apfel,

Commissioner of Social Security.

[FR Doc. 01–318 Filed 1–4–01; 8:45 am]

BILLING CODE 4191–02–U

DEPARTMENT OF STATE

[Public Notice #3520]

Secretary of State's Advisory Committee on Private International Law Renewal

The Department of State has renewed the Charter of the Secretary of State's Advisory Committee on Private International Law (ACPIL). The Under Secretary for Management has determined that ACPIL is necessary and in the public interest.

ACPIL will continue to assist the Department to coordinate effective United States participation in international efforts to unify private law between nations. ACPIL enables the Department to obtain the expert and considered views of private sector interests most knowledgeable of, as well as most affected by, international activities in this field.

ACPIL consists of members of private sector organizations, bar associations, national legal organizations, and federal and state government agency and judicial interests concerned with private international law. ACPIL will follow the procedures prescribed by the Federal Advisory Committee Act (FACA) (Pub. L. 92–463). Meetings will be open to the public unless a determination is made in accordance with Section 10(d) of the FACA, 5 U.S.C. 552b(c)(1) and (4), that a meeting or a portion of the meeting should be closed to the public.

For more information, please contact Harold Burman, Executive Director ACPIL, Office of the Legal Adviser, 2430 E Street, NW, South Bldg., Suite 203, Washington, DC 20037–2851, phone 202 776–8420.

Jeffrey D. Kovar,

Assistant Legal Adviser for Private International Law, Department of State.

[FR Doc. 01–353 Filed 1–4–01; 8:45 am]

BILLING CODE 4710–08–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG–2000–8574]

Navigation Safety Advisory Council; Vacancies

AGENCY: Coast Guard, DOT.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the Navigation Safety Advisory Council (NAVSAC). NAVSAC advises the Coast Guard on the prevention of vessel collisions, rammings, and groundings; Inland Rules of the Road; International Rules of the Road; navigation regulations and equipment; routing measures; marine information; diving safety; and aids to navigation systems.

DATES: Application forms should reach us on or before February 16, 2001.

ADDRESSES: You may request an application form by writing to Commandant (G–MW), U.S. Coast Guard, 2100 Second Street SW., Washington, DC 20593–0001; by calling 202–267–6164; by faxing 202–267–4700; or by e-mail *Jshort@comdt.uscg.mil.* Send your application in written form to the above street address. This notice and the application form are available on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Margie Hegy, Executive Director of NAVSAC at (202) 267–0415, fax (202) 267–4700.

SUPPLEMENTARY INFORMATION: The Navigation Safety Advisory Council (NAVSAC) is a Federal advisory committee under 5 U.S.C. App. 2. It advises the Secretary of Transportation, via the Commandant of the Coast Guard, on the prevention of vessel collisions, rammings, and groundings; Inland Rules of the Road; International Rules of the Road; navigation regulations and equipment; routing measures; marine information; diving safety; and aids to navigation systems.

NAVSAC meets at least twice a year at various locations in the continental United States. It may also meet for extraordinary purposes. Its subcommittees and working groups may meet to consider specific problems as required.

We will consider applications for seven positions that expire or become vacant in June 2001. To be eligible, you should have experience in the above mentioned subject areas. To assure balanced representation of subject matter expertise, members are chosen, insofar as practical, from the following groups: (1) Recognized experts and leaders in organizations having an active interest in the Rules of the Road and vessel and port safety; (2) representatives of owners and operators of vessels, professional mariners, recreational boaters, and the recreational boating industry; (3) individuals with an interest in maritime law; and (4) Federal and State officials with responsibility for vessel and port safety. Each member serves for a term of 3 years. A few members may serve consecutive terms. All members serve without compensation from the Federal Government, although travel reimbursement and per diem may be provided.

In support of the policy of the Department of Transportation on gender and ethnic diversity, we encourage qualified women and members of minority groups to apply.

Dated: December 26, 2000.

J.P. High,

Acting Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 01–67 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Passenger Facility Charge (PFC) Approvals and Disapprovals

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Monthly Notice of PFC Approvals and Disapprovals. In November 2000, there were five applications approved. This notice also includes information on two applications, approved in October 2000, inadvertently left off the October 2000 notice. Additionally, 21 approved amendments to previously approved applications are listed.

SUMMARY: The FAA publishes a monthly notice, as appropriate, of PFC approvals and disapprovals under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158). This notice is published pursuant to paragraph d of § 158.29.

PFC Applications Approved

Public Agency: County of Del Norte, Crescent City, California.

Application Number: 00–02–C–00–CEC.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total PFC Revenue Approved in this Decision: $447,048.

Earliest Charge Effective Date: January 1, 2001.

Estimated Charge Expiration Date: July 1, 2013.

Class of Air Carriers Not Required to Collect PFC's: None.

Brief Description of Projects Approved for Collection and Use:

Install replacement fuel system
Install security fencing—phase 1
Reconstruct and expand automobile parking lot
Airport layout plan update
Terminal building renovation
Environmental study (airport south development)
New terminal building—preliminary design and studies
Install security fencing—phase II
Acquire safety equipment (tractor and sweeper)
Fire suppression water lines
Install runway guidance system precision approach path indicator, runway 35

Brief Description of Project Withdrawn: Install 50,000-gallon water tank.

Determination: This project was withdrawn by the public agency from the application by letter dated October 23, 2000. Therefore, the FAA did not rule on this project in this Record of Decision.

Discussion Date: October 30, 2000.

FOR FURTHER INFORMATION CONTACT: Marlys Vandervelde, San Francisco Airports District Office, (650) 876–2806.

Public Agency: City of Elko, Nevada.

Application Number: 00–02–C–00–EKO.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total PFC Revenue Approved in this Decision: $6,194,920.

Earliest Charge Effective Date: February 1, 2001.

Estimated Charge Expiration Date: September 1, 2018.

Class of Air Carriers Not Required to Collect PFC's: None.

Brief Description of Projects Approved for Collection and Use:

Terminal building expansion, phases II–IV
Terminal access road—phase II
Master drainage study
Commercial apron and connecting taxiways
Terminal building

Decision Date: October 30, 2000.

FOR FURTHER INFORMATION CONTACT: Marlys Vandervelde, San Francisco Airports District Office, (650) 876–2806.

Public Agency: Huntsville-Madison County Airport Authority, Huntsville, Alabama.

Application Number: 00–10–C–00–HSV.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total PFC Revenue Approved in this Decision: $1,498,644.

Earliest Charge Effective Date: June 1, 2009.

Estimated Charge Expiration Date: April 1, 2013.

Class of Air Carriers Not Required to Collect PFC's: (1) air taxi/commercial operators; (2) certified air carriers; and (3) certified route air carriers having fewer than 500 annual passenger enplanements at Huntsville International Airport (HSV).

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that each approved class accounts for less than 1 percent of the total annual enplanements at HSV.

Brief Description of Projects Approved for Collection and Use:

Security vehicle 2000 and body armor
Taxiway C crossfield connector
Air cargo expansion III
Bag Claim expansion/terminal renovation
Air carrier apron rehabilitation
Access road rehabilitation

Decision Date: November 9, 2000.

FOR FURTHER INFORMATION CONTACT: Roderick T. Nicholson, Jackson Airports District Office, (601) 664–9884.

Public Agency: Duluth Airport Authority, Duluth, Minnesota.

Application Number: 00–04–C–00–DLH.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total PFC Revenue Approved in this Decision: $577,702.

Earliest Charge Effective Date: December 1, 2000.

Estimated Charge Expiration Date: September 1, 2002.

Class of Air Carriers Not Required to Collect PFC'S: Non-scheduled Part 135 air taxi/commercial operators.

Determination: Approved. Based on the information in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Duluth International Airport.

Brief Description of Projects Approved for Collection and Use:

Purchase snowblower (snow removal equipment).
Purchase runway sander (snow removal equipment).
Security upgrade to terminal building.
PFC consultation fees.

Brief Description of Projects Partially Approved for Collection and Use:

Runway 9/27 centerline and touchdown zone lighting (design and phase I construction).

Determination: The approved amount is less than that requested because the total cost listed in the application included costs for elements of work not included in the PFC project description. The approved amount was limited to costs associated with the approved project elements.

Install runway 9/27 centerline and touchdown lighting.

Determination: The approved amount is less than that requested because the

total cost listed in the application included costs for elements of work not included in the PFC project description. The approved amount was limited to costs associated with the approved project elements.

Brief Description of Disapproved Project: Design Category II instrument landing system.

Determination: The FAA has determined that activity levels under Category II conditions at Duluth International Airport do not meet the criteria for FAA establishment of a Category II instrument landing system for runway 9. Therefore, this project is disapproved.

Decision Date: November 13, 2000.

FOR FURTHER INFORMATION CONTACT: Gordon Nelson, Minneapolis Airports District Office, (612) 713–4358.

Public Agency: Chattanooga Metropolitan Airport Authority, Chattanooga, Tennessee.

Application Number: 00–03–C–00–CHA.

Application Type: Impose and use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved in this Decision: $23,427,223.

Earliest Charge Effective Date: February 1, 2005.

Estimated Charge Expiration Date: May 1, 2015.

Class of Air Carriers Not Required to Collect PFC's: (1) Air carriers operating under part 135 on an on-demand, non-scheduled, whole plane charter basis, and not selling tickets to individual passengers; (2) air carriers operating under part 298 on an on-demand, non-scheduled, whole plane charter basis, and not selling tickets to individual passengers.

Determination: Approved. Based on the information in the public agency's application, the FAA has determined each of the approved classes accounts for less than 1 percent of the total annual enplanements at Chattanooga Metropolitan Airport.

Brief Description of Projects Approved for Collection and Use:

Land acquisition—Honest Street.
Airside site work and development.
Land acquisition—Chickamauga.
Relocation of taxiway A.
Target property.
Access road—west airfield development.
Obstruction removal.
Levee improvements.
Part 150 program.

Brief Description of Projects Approved for Collection: Roadway improvements.

Decision Date: November 22, 2000.

FOR FURTHER INFORMATION CONTACT: Cager Swauncy, Memphis Airports District Office, (901) 544–3495.

Public Agency: Rhode Island Airport Corporation, Warwick, Rhode Island.

Application Number: 00–03–C–00–PVD.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total PFC Revenue Approved in this Decision: $41,689,000.

Earliest Charge Effective Date: April 1, 2008.

Estimated Charge Expiration Date: August 1, 2012.

Class of Air Carriers Not Required to Collect PFC's: Air taxi.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at the T.F. Green State Airport (PVD).

Brief Description of Project Approved for Collection at PVD and Use at PVD:

Noise mitigation land acquisition.
North ramp rehabilitation.
PFC application.

Brief Description of Project Approved for Collection at PVD for Future Use at PVD:

New airfield maintenance facilities.
Ticket counter expansion.

Brief Description of Project Approved for Collection at PVD for Future Use at Westerly State Airport: Rehabilitation of apron and taxiways B and C.

Brief Description of Project Approved for Collection at PVD for Future Use at Block Island State Airport: Expansion of apron and construct taxiway to runway 10.

Brief Description of Project Approved for Collection at PVD for Future Use at North Central State Airport: Rehabilitation of apron.

Brief Description of Project Approved for Collection at PVD for Future Use at Quonset State Airport: Rehabilitation of apron.

Decision Date: November 27, 2000.

FOR FURTHER INFORMATION CONTACT: Priscilla Scott, New England Region Airports Division, (781) 238–7614.

Public Agency: Port of Friday Harbor, Friday Harbor, Washington.

Application Number: 00–01–C–00–FRD.

Application Type: Impose and use a PFC.

PFC Level: $3.00.

Total PFC Revenue Approved In This Decision: $226,806.

Earliest Charge Effective Date: February 1, 2001.

Estimated Charge Expiration Date: November 1, 2005.

Class of Air Carriers Not Required To Collect PFC'S: None.

Brief Description of Projects Approved for Collection and Use:

Purchase airport land (parcels 44, 46, and 50).
Purchase airport land (parcel 37).
Purchase airport land (parcels 47 and 49).
Storm water handling system improvements.
Runway overlay (design only).
Runway safety area improvements, runway 16/34.
Taxiway lighting and signage.
Purchase snow removal equipment.
Interactive personnel training system.
Rehabilitate runway, taxiway, and aprons.
Security fencing.

Decision Date: November 20, 2000.

FOR FURTHER INFORMATION CONTACT: Suzanne Lee-Pang, Seattle Airports District Office, (425) 227–2654.

AMENDMENTS TO PFC APPROVALS

Amendment No. city, state	Amendment approved date	Original approved net PFC revenue	Amended approved net PFC revenue	Original estimated charge exp. date	Amendment estimated charge exp. date
92–01–1–06–HSV, Huntsville, AL	09/13/00	$19,930,558	$15,353,674	01/01/03	01/01/03
97–07–U–01–HSV, Huntsville, AL	09/13/00	NA	NA	NA	NA
99–09–C–01–HSV, Huntsville, AL	09/13/00	557,969	777,615	11–01/03	11/01/03
99–04–C–01–BGM, Binghamton, NY	01/06/00	4,694,436	4,714,684	04/01/06	04/01/06
00–02–C–01–SWF, Newburgh, NY	10/10/00	4,558,000	6,308,000	12/01/00	02/01/05
93–01–C–02–JAX, Jacksonville, FL	10/19/00	12,309,429	11,541,949	07/01/97	08/01/96
96–02–C–02–JAX, Jacksonville, FL	10/19/00	17,758,250	18,503,092	09/01/00	06/01/99
93–01–C–01–PVD, Warwick, RI	11/09/00	103,885,286	104,397,014	08/01/13	11/01/07

AMENDMENTS TO PFC APPROVALS—Continued

Amendment No. city, state	Amendment approved date	Original approved net PFC revenue	Amended approved net PFC revenue	Original estimated charge exp. date	Amendment estimated charge exp. date
98–03–C–03–CRW. Charleston, WV	11/14/00	662,687	665,222	03/01/99	03/01/99
98–04–C–01–CRW. Charleston, WV	11/14/00	1,257,285	1,253,835	01/01/01	01/01/01
98–05–U–02–CRW, Charleston, WV	11/14/00	NA	NA	NA	NA
00–06–C–01–CRW, Charleston, WV	11/14/00	992,810	1,051,081	08/01/02	08/01/02
98–02–C–01–FLL, Fort Lauderdale, FL	11/15/00	190,129,976	191,105,272	11/01/07	11/01/07
97–01–C–01–SDF. Louisville, KY	11/15/00	40,000,000	90,600,000	05/01/07	01/01/15
*97–03–C–01–EGE, Eagle, CO	11/17/00	8,132,130	8,132,130	03–01–12	06–01–09
95–03–C–01–SYE, Syracuse, NY	11/12/00	6,239,050	6,737,425	04/01/97	04/01/97
96–02–C–01–SYR, Syracuse, NY	11/21/00	7,887,547	8,019,927	02/01/01	02/01/01
98–03–U–01–SYR, Syracuse, NY	11/21/00	NA	NA	NA	NA
*93–01–C–02–CHA, Chattanooga, TN	11/21/00	8,568,925	9,550,221	07/01/05	11/01/04
*99–03–C–01–ALO, Waterloo, IA	11/27/00	763,830	763,830	11/01/03	05/01/03
*99–03–C–01–DUJ, Du Bois, PA	11/29/00	172,710	160,109	06/01/03	2/01/03

(Note: The amendments denoted by an asterisk (*) include a change to the PFC level charged from $3.00 per enplaned passenger to $4.50 per enplaned passenger. For Eagle, CO, Chattanooga, TN, and Du Bois, PN, this change is effective on April 1, 2001. For Waterloo, IA, this change is effective on July 1, 2001.)

Issued in Washington, DC, on December 28, 2000.

Eric Gabler,

Manager, Passenger Facility Charge Branch.

[FR Doc. 01–268 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application (01–07–C–00–JAC) To Impose and To Use a Passenger Facility Charge (PFC) at the Jackson Hole Airport, Submitted by the Jackson Hole Airport Board, Jackson, WY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to use a PFC at the Jackson Hole Airport under the provisions of 49 U.S.C. 40117 and Part 158 of the Federal Aviation Regulations (14 CFR 158).

DATES: Comments must be received on or before February 5, 2001.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Alan Wiechmann, Manager; Denver Airports District Office, DEN–ADO; Federal Aviation Administration; 26805 E. 68th Avenue, Suite 224; Denver, CO 80249–6361.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. George Larson, Airport Director, at the following address: Jackson Hole Airport Board, P.O. Box 159, Jackson, Wyoming 83001.

Air Carriers and foreign air carriers may submit copies of written comments previously provided to Jackson Hole Airport, under section 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Schaffer, (303) 342–1258; Denver Airports District Office, DEN–ADO; Federal Aviation Administration; 26805 E. 68th Avenue, Suite 224; Denver, CO 80249–6361. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application (01–07–C–00–JAC) to use a PFC at the Jackson Hole Airport, under the provisions of 49 U.S.C. 40117 and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

On December 27, 2000, the FAA determined that the application to impose a PFC submitted by the Jackson Hole Airport Board, Jackson Hole Airport, Jackson, Wyoming, was substantially complete within the requirements of section 158.25 of Part 158. The FAA will approve or disapprove the application, in whole or in part, no later than March 30, 2001.

The following is a brief overview of the application.

Level of the proposed PFC: $4.50.

Proposed charge effective date: June 1, 2002.

Proposed charge expiration date: January 1, 2003.

Total requested for use approval: $190,430.00.

Brief description of proposed project: Install medium intensity approach lighting system; air carrier apron reconstruction; snow removal equipment.

Class or classes of air carriers which the public agency has requested not be required to collect PFC's: None.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA Regional Airports Office located at: Federal Aviation Administration, Northwest Mountain Region, Airports Division, ANM–600, 1601 Lind Avenue SW., Suite 540, Renton, WA 98055–4056.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Jackson Hole Airport.

Issued in Renton, Washington on December 27, 2000.

David A. Field,

Manager, Planning, Programming and Capacity Branch, Northwest Mountain Region.

[FR Doc. 01–349 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Policy Statement Number ACE–00–23.901(d)(2)]

Issuance of Policy Memorandum, Notice of Compliance with the Engine Ingestion Requirements Applicable to Turbine Powered, 14 CFR Part 23, Normal, Utility, Acrobatic, and Commuter Category Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of policy statement.

SUMMARY: This document announces an FAA general statement of policy applicable to turbine powered, normal, utility, acrobatic, and commuter category airplanes. This document advises the public, in particular, small airplane owners and modifiers, of more information related to compliance with the engine ingestion requirements applicable to turbine powered, part 23, normal, utility, acrobatic, and commuter category airplanes. This notice is necessary to tell the public of FAA policy.

FOR FURTHER INFORMATION CONTACT: Randy Griffith, Federal Aviation Administration, Small Airplane Directorate, Regulations and Policy Branch, ACE–111, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone (816) 329–4126; fax (816) 329–4090; email: <randy.griffith@faa.gov>.

SUPPLEMENTARY INFORMATION:

Background

This notice announces the following policy statement, ACE–00–23.901(d)(2). The purpose of this statement is to address compliance with the engine ingestion requirements applicable to turbine powered, part 23, normal, utility, acrobatic, and commuter category airplanes.

What Is the General Effect of This Policy?

The FAA is presenting this information as a set of guidelines suitable for use. However, we do not intend that this policy set up a binding norm; it does not form a new regulation and the FAA would not apply or rely on it as a regulation.

The FAA Aircraft Certification Offices (ACO's) and Flight Standards District Offices (FSDO's) that certify changes in type design and approve alterations in normal, utility, and acrobatic category airplanes should try to follow this policy when appropriate. Applicants should expect the certificating officials would consider this information when making findings of compliance relevant to compliance with the engine ingestion requirements applicable to turbine powered, part 23, normal, utility, acrobatic, and commuter category airplanes.

As with all advisory material, this statement of policy identifies one way, but not the only way, of compliance.

General Discussion of Comments

Has FAA Taken Any Action to This Point?

We issued a notice of policy statement, request for comments. This proposed policy appeared in the **Federal Register** on September 1, 2000 (65 FR 53338) and the public comment period closed October 2, 2000.

Was The Public Invited To Comment?

The FAA encouraged interested people to join in making this proposed policy. We received one comment. The commenter, while fully agreeing with the content, noted that the policy would be better if in an FAA Advisory Circular. We have noted the commenter's concerns. We will eventually provide the pertinent information in this policy in a revision to Advisory Circular 23–16, Powerplant Guide for Certification of Part 23 Airplanes. In the interim, the issuance of a policy statement is more timely and effective. Additionally, experience with a recent certification project resulted in further clarification of the draft policy. As a result, we have explained compliance considerations related to critical conditions for turbopropeller engine installations as compared to turbojet/fan engine installations. If these added compliance considerations cause concern, please send your comments to <randy.griffith@faa.gov>.

The Policy

Background

The current § 23.901(d)(2) requirement was incorporated by Amendment 23–53. However, the basic requirement, which has evolved into the current § 23.901(d)(2), was incorporated by Amendment 23–18.

Amendment 23–18 required that the engine installation provide continued engine operation without a sustained loss of power when operated at flight idle in rain for at least three minutes. The rate of rain ingestion was to be not less than 4 percent, by weight, of the engine induction airflow rate. The rule was incorporated due to reports of turbine engine power loss while operating in heavy rain. The intent of the rule was twofold: (1) to ensure that installation effects do not result in deterioration of the engine's rain ingestion tolerance determined by engine certification; and (2) to evaluate the engine's capability for rain ingestion for engines that were certificated before Amendment 33–6 since rain ingestion requirements were not added to 14 CFR part 33 until Amendment 33–6. Therefore, the rate of rain ingestion to be considered was based upon the part 33 engine certification requirement at the time.

Revisions of Standards

Amendment 23–29 revised the requirement to consider rated takeoff power/thrust. Also, the preamble to Amendment 23–29 further defined the intent of § 23.901(d)(2) by specifically stating that the rule is to ensure that installation effects do not result in any deterioration of the powerplant rain ingestion tolerance. Therefore, compliance with § 23.901(d)(2) required a separate determination for engine installation other than the requirements addressed by part 33 (for example, engine certification without further installation certification is inadequate to demonstrate compliance with the part 23 requirement).

Amendment 23–43 added a requirement that the installation be evaluated at the maximum installed power/thrust for takeoff. This new requirement was due to engine installations where rated takeoff power could be less than installed takeoff power; for example, de-rate thrust. The amendment also added a requirement that the engine be accelerated and decelerated safely under the rain conditions; however, Amendment 23–51 removed this consideration.

Amendment 23–53 added the current rule. The current amendment requires the installed engine to withstand ingestion of rain, hail, ice, and birds at a level not less than that established under engine certification. The significant changes with the new rule include operating concerns other than loss of power (for example, engine surges), the addition of hail, ice, and bird ingestion requirements, and replacement of specific rain quantification with the conditions used during engine certification. Under Amendment 23–53, the airplane applicant needs to evaluate the conditions used to address rain, hail, ice, and bird ingestion during engine certification and how the installation relates to these conditions.

Means of Compliance

When showing compliance with the rain ingestion requirements for all amendment levels of § 23.901(d)(2), compliance is typically accomplished with design analysis that identifies areas of concern and test when there are areas of concern. Part 33 engine certification testing may be used for compliance if the engine certification testing (1) addressed the areas of concern identified by the installation design analysis (for example, use of an installation representative test inlet system) and (2) specific conditions addressed in the rule were addressed

during engine certification testing. For airplanes with a certification basis prior to Amendment 23–53, test is typically required if the specific operating considerations contained in the part 23 rule were not addressed during engine certification.

When evaluating areas of concern with the installation, consider areas where water pooling with subsequent ingestion or shed of localized ''slugs'' of water normally not addressed during engine certification might occur. Some examples are inlet system channels, indentations, and so forth. These are typical of turbopropeller or S-duct type inlets that have complex geometry to allow water pooling. This consideration is usually not a concern with simple pitot style inlets typical of most part 23 turbofan/jet engine installations. However, due to the large diversity of turbine engine installations in part 23 airplanes, all installations should be evaluated to determine if areas of concern exist. For example, there are turbofan installations that use S-style inlet ducts that may have areas of concern.

Therefore, part 23 turbine engine installations typically require testing since the vast majority of these are turbopropeller installations. However, if design analysis shows that the installation will not affect the water ingestion characteristics (for example, a simple and typical pitot style inlet installation) and engine certification addressed the specific conditions addressed in the part 23 rule, this analysis combined with engine certification testing may be adequate to demonstrate rain ingestion compliance.

Also, since the rain ingestion requirements in part 33 were not added until Amendment 33–6, the airplane applicant needs to evaluate the engine's certification basis to determine if the engine has been subjected to part 33 rain ingestion testing. If the engine does not have Amendment 33–6 or a subsequent amendment as part of the certification basis, in accordance with § 23.903(a)(2)(iii), the engine must have a safe service history of rain ingestion in similar installations.

If it is determined that testing for rain ingestion should be performed, flight test is not required. The intent of the part 23 rule is to ensure that the engine installation has not deteriorated the rain ingestion tolerance of the certificated engine. Since a ground static engine test normally demonstrates engine certification compliance, use of installation ground tests at the required power/thrust settings has been commonly accepted as a means of compliance.

The applicant can use design analysis to determine critical configurations and conditions of the installation. This might reduce required installation tests to the critical configurations and conditions instead of repeating the entire part 33 test conditions. Engine certification should address the results of the critical point analysis for the engine; therefore, it is important for the engine installer to research the conditions and requirements used for engine certification.

Other Considerations for Compliance

Amendment 23–53 also added requirements for ice, hail, and birds. Examples of installation issues normally not addressed by engine certification, but that should be addressed for installation compliance, include the following: ice build-up on areas where ice shed may be ingested by the engines (for example, ice shed from wings and airframe sources into aft mounted engines) and consideration of items such as inlet splitters, acoustic liners, and so forth, that may be damaged by impact with ice, hail, and birds.

Issued in Kansas City, Missouri on December 14, 2000.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–347 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Rensselaer County, NY

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed highway project in Rensselaer County, New York.

FOR FURTHER INFORMATION CONTACT:

Thomas C. Werner, Regional Director, New York State Department of Transportation, Region One, 84 Holland Avenue, Albany, New York 12208, Telephone: (518) 474–6178.

or

A. Graham Bailey, Acting Division Administrator, Federal Highway Administration, New York Division, Leo W. O'Brien Federal Building, 7th Floor, Clinton Avenue and North Pearl Street, Albany, New York 12207, Telephone: (518) 431–4127.

SUPPLEMENTARY INFORMATION: The FHWA in cooperation with the New York State Department of Transportation (NYSDOT), will be preparing an Environmental Impact Statement (EIS) in accordance with the National Environmental Policy Act (NEPA) on a proposal to provide a new connector road to Interstate 90 (I–90), in Rensselaer County, New York. The proposed improvement would involve the construction of a new limited access highway that extends from the terminus of the existing Interstate 90 Exit 8 at Route 43 northerly on an alignment about ½ mile west of Route 4 and curving northeasterly to an intersection with Route 4 in the vicinity of the Hudson Valley Community College (HVCC), a distance of 5.1 km (3 miles). Improvements to the corridor are considered necessary to provide for the projected traffic demand. Project objectives include reducing forecast congestion and promoting economic development along the Route 4 corridor, supporting the land use goals and master plans of local communities, and improving mobility for pedestrians, bicyclists, and transit users. The project also seeks to establish an Intelligent Transportation System (ITS) ''in situ laboratory facility'' on the new roadway and segments of the other existing area roadways.

Alternatives under consideration include: (1) providing a new limited access highway from the terminus of the existing Interstate 90 Exit 8 northerly to terminate at Route 136 (Williams Road); (2) providing a new limited access highway from the terminus of the existing Interstate 90 Exit 8 northerly to the vicinity of the Hudson Valley Community College (HVCC). Incorporated into and studied with the alternatives will be design variations of grade and alignment and intersection modifications.

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and local agencies, and to private organizations and citizens who have previously expressed interest in this proposal. Also planned are early coordination and exchanges of information meetings, direct requests to other agencies to become cooperating agencies, and early notification and solicitation with entities affected by the proposed action through the clearinghouse process. A series of public information meetings and public hearings will be held between January and December, 2001. Public notice will be given of the time and place of the meetings and hearings. The draft EIS will be available for public and agency review and comment. No

formal scoping meeting is planned at this time.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the NYSDOT or FHWA at the addresses provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation Federal Programs and activities apply to this program.)

Authority: 23 U.S.C. 315; U.S.C. 771.123.

Issued on: December 18, 2000.

Douglas P. Conlan,

District Engineer, Federal Highway Administration, Albany, New York.

[FR Doc. 01–291 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2000–8494]

Transportation Equity Act for the 21st Century; Implementation Guidance for Financial Plans of Mega Projects

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of availability of guidance with request for comment.

SUMMARY: This document provides notice of the availability of implementation guidance on financial plans for Federal highway projects with an estimated total cost of $1 billion or more (mega projects). This guidance provides information and assistance to the States in preparing the annual financial plan for projects as required by section 1305(b) of the Transportation Equity Act for the 21st Century (TEA–21).

DATES: Comments must be submitted on or before March 2, 2001.

ADDRESSES: Mail or hand deliver comments to the docket number that appears in the heading of this document to the U.S. Department of Transportation, Dockets Management Facility, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590, or submit electronically at *http://dmses.dot.gov/submit.* All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically.

FOR FURTHER INFORMATION CONTACT: Ms. Carol Jacoby, Contract Administration Group Leader, HIPA–30, (202) 366–1561; or Mr. Harold Aikens, Office of the Chief Counsel, HCC–30, (202) 366–0791. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

You may submit or retrieve comments online through the Document Management System (DMS) at: *http://dmses.dot.gov/submit.* Acceptable formats include: MS Word (versions 95 to 97), MS Word for Mac (versions 6 to 8), Rich Text File (RTF), American Standard Code Information Interchange (ASCII)(TXT), Portable Document Format (PDF), and WordPerfect (versions 7 to 8). The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the web site.

An electronic copy of this document may also be downloaded by using a computer, modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may also reach the Office of the Federal Register's home page at: *http://www.nara.gov/fedreg* and the Government Printing Office's web site at: *http://www.access.gpo.gov/nara.*

Availability of Guidance

The financial plan guidance may be obtained by calling (202) 366–1561 or may be viewed at the FHWA web page as follows: *http://www.fhwa.dot.gov/infrastructure.*

Background

Section 1305(b) of the TEA–21, Public Law 105–178, 112 Stat. 107 at 229, was signed into law on June 9, 1998, and modified 23 U.S.C. 106 by adding subsection (h), which requires that a recipient of Federal financial assistance for a project with an estimated total cost of $1 billion or more submit to the Secretary of Transportation an annual financial plan for the project. The TEA–21 requires that the plan be based on detailed annual estimates of the cost to complete the remaining elements of the project and on reasonable assumptions of future increases in the cost to complete the project. Current and potential funding shortfalls must be identified, and future financial resources must be committed to fund the completion of the project.

The content and format of the Initial Financial Plan, annual updates, and core exhibits is intended to encourage consistency in the way the documents are prepared. This consistency of content and format will allow for ease of understanding and review by the U.S. DOT Office of the Secretary, the Congress, the upper echelon of transportation executives, and professionals who routinely deal with these projects.

This guidance is effective immediately for all mega projects with construction less than fifty percent complete as of May 31, 2000. Revisions to this guidance may be made in the future after the initial implementation, and pending receipt of significant comments.

Authority: 23 U.S.C. 106(h) and 315; 49 CFR 1.48.

Issued on: January 2, 2001.

Kenneth R. Wykle,

Federal Highway Administrator.

[FR Doc. 01–393 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Best Practices Procurement Manual; Conflicts of Interest Guidance

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice and request for comments on proposed updates to FTA's Best Practices Procurement Manual; Conflicts of Interest.

SUMMARY: The Federal Transit Administration (FTA) is developing additional guidance on identifying and addressing real and apparent conflicts of interest on contracts involving federal financial assistance. FTA is seeking input from interested parties on this issue, including examples of problems and best practices for avoiding and/or dealing with conflicts of interest. Upon consideration of the comments, FTA will issue additional guidance on conflicts of interest for inclusion in the FTA Best Practices Procurement Manual.

DATES: Comments must be received on or before February 28, 2001.

ADDRESSES: The draft guidance material is available for public review on the

Internet at *http://www.fta.dot.gov/library/procurement/conflicts.html*. Written comments may be addressed to Lucy T. Jackson, Director, Office of Procurement, Federal Transit Administration, TAD–40, Room 9101, 400 Seventh Street, SW., Washington, DC 20590, and shall reference this notice. Alternatively, you may send comments electronically to [*conflictsofinterest@fta.dot.gov*].

FOR FURTHER INFORMATION CONTACT: Lucy T. Jackson, Office of Procurement, (202) 366–4980, or Donald R. Durkee, Office of Chief Counsel, (202) 366–1936.

SUPPLEMENTARY INFORMATION: Responding to requests from transit industry representatives, FTA is in the process of developing further guidance on handling conflicts of interest on contracts involving federal financial assistance. Currently, FTA's Best Practices Procurement Manual contains only a brief discussion on conflicts of interest issues. Given the importance of this issue, FTA intends to promulgate additional guidance. The additional coverage will include further discussion of the requirements as established in the FTA Circular 4220.1D, the FTA Master Agreement, and the Code of Federal Regulations, 49 CFR parts 18 and 19; definition of terms; examples and scenarios of various types of conflicts and remedies or solutions to conflicts. This guidance, based on input received from interested parties, will then be incorporated into FTA's Best Practices Procurement Manual. To assist in this endeavor, FTA has established a web page containing the draft guidance along with preliminary definitions and examples that FTA believes might be included in the Best Practices Procurement Manual.

Issued on: December 29, 2000.

Nuria I. Fernandez,

Acting Administrator, Federal Transit Administrator.

[FR Doc. 01–269 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–01–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2000–8561]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collections of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under new procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections.

This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before March 6, 2001.

ADDRESSES: Comments must refer to the docket and notice numbers cited at the beginning of this notice and be submitted to Docket Management, room PL–401, 400 Seventh St. SW., Washington, DC 20590. Please identify the proposed collection of information for which a comment is provided, by referencing its OMB Clearance Number. It is requested, but not required, that 1 original plus 2 copies of the comments be provided. The Docket Section is open on weekdays from 10:00 a.m. to 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Complete copies of the request for collection of information may be obtained at no charge from Mr. Samuel Daniel, NHTSA, 400 Seventh Street, SW., room 5313, Washington, DC 20590. Mr. Daniel's telephone number is (202) 366–4921. Please identify the relevant collection of information by referring to its OMB Clearance Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) how to enhance the quality, utility, and clarity of the information to be collected; and

(iv) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

Motor Vehicle Brake Fluid Container Labeling

49 CFR 571.116

Type of Request—Reinstatement of clearance.

OMB Clearance Number—2127–0521.

Form Number—This collection of information uses no standard forms.

Requested Expiration Date of Approval—Three years from date of approval.

Summary of the Collection of Information—Federal Motor Vehicle Safety Standard No. 116, ''Motor Vehicle Brake Fluids,'' specifies performance and design requirements for motor vehicle brake fluids and hydraulic system mineral oils. Section 5.2.2 specifies labeling requirements for manufacturers and packagers of brake fluids as well as packagers of hydraulic system mineral oils. The information on the label of a container of motor vehicle brake fluid or hydraulic system mineral oil is necessary to insure the following: the contents of the container are clearly stated; these fluids are used for their intended purpose only; and, the containers are properly disposed of when empty. Improper use or storage of these fluids could have dire safety consequences for the operators of vehicles or equipment in which they are used.

Description of the need for the information and proposed use of the information—This labeling information is used by motor vehicle owners, operators, and vehicle service facilities to aid in the proper selection of brake fluids and hydraulic system mineral oils for use in motor vehicles and hydraulic equipment, to assure the continued safety of motor vehicle braking and hydraulic systems, respectively. The information required on brake fluid and hydraulic mineral oil containers includes the performance capabilities of the fluid. There are also safety warnings required on brake fluid and hydraulic system mineral oil containers to prevent improper use, storage, etc. which might

result in motor vehicle brake failure and the failure of equipment utilizing hydraulic system mineral oil.

Properties of these fluids and their use necessitate the package labeling information specified in this standard. Brake fluid and hydraulic system mineral oil must be free of contaminants in order to perform as intended; therefore, the labeling instructions warn against storing in unsealed containers or mixing these fluids with other products. Also, avoiding the absorption of moisture is extremely important since moisture in a brake system degrades braking performance and safety by lowering brake fluid's boiling point, increasing the fluid's viscosity at low atmospheric temperatures and increasing the risk of brake system component corrosion. Lower boiling points increase the risk of brake system failure by increasing the possibility of vapor lock and resultant loss of pressure in the brake system. The safety warnings also alert users of brake fluids sold in containers with capacities of less than five gallons that the containers should not be refilled or reused for other purposes.

If the labeling requirements were not mandatory, maintaining the current level of brake safety on the nation's highways would be more difficult. Proper vehicle brake performance is crucial to the safety of motor vehicle occupants, and the information on fluid containers is necessary to aid in reducing brake system failures resulting from the use of improper or contaminated fluid. The labeling on fluid containers also helps to ensure that only fluid that complies with federal requirements is sold, and this also facilitates agency enforcement efforts by identifying the fluid packager, manufacturer, and date of manufacture.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information—There are an estimated 200 respondents, mainly those manufacturers and packagers involved with the production of motor vehicle brake and hydraulic fluids. A label is required on each container of fluid sold.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting from the Collection of Information—The total annualized cost to respondents is estimated by the agency to be $372,370 which includes a labor burden and material costs. The labor burden is estimated to be 7,680 hours performed by a total of 200 respondents. The labor burden involves the designing of labels for each label redesign cycle at an estimated cost of $38.00 per hour. The estimated annual labor burden is therefore $291,840 and the cost of materials, primarily ink for label printing, is estimated to be $402.65 per respondent for an annual total of $80,530.

Authority: 44 U.S.C. 3506(c); delegation of authority at 49 CFR 1.50.

Issued: December 29, 2000.

Noble N. Bowie,

Acting Associate Administrator for Safety Performance Standards.

[FR Doc. 01–344 Filed 1–4–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33983]

Landisville Terminal & Transfer Company—Lease and Operation Exemption—Landisville Railroad Inc.

Landisville Terminal & Transfer Company (LAND), a noncarrier, newly created to become a Class III railroad, has filed a notice of exemption under 49 CFR 1150.31 to lease and operate less than two miles of rail line currently owned by Landisville Railroad Inc. (LRC) in Lancaster County, PA. The rail line consists of LRC's entire rail line between its connection to Norfolk Southern Railway Company on Amtrak's Harrisburg Line and the end of track south of Nolt Road and north of Stony Battery Road. LAND certifies that its projected annual revenues will not exceed those that would qualify it as a Class III rail carrier and that its annual revenues are not projected to exceed $5 million.

LAND indicates that it is leasing all of LRC's assets and will continue to provide the common carrier railroad service currently provided by LRC over its property.

The transaction is expected to be consummated on or about January 1, 2001.

If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33983, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on John D. Heffner, REA, CROSS & AUCHINCLOSS, 1707 L Street, NW., Suite 570, Washington, DC 20036.

Board decisions and notices are available on our website at ''*www.stb.dot.gov.*''

Decided: December 28, 2000.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 01–211 Filed 1–4–01; 8:45 am]

BILLING CODE 4915–00–P

Federal Register

Friday,

January 5, 2001

Part II

Department of Agriculture

Agricultural Marketing Service

7 CFR Part 54

Regulations Governing the Certification of Sanitary Design and Fabrication of Equipment Used in the Processing of Livestock and Poultry Products; Final Rule

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 54

[Docket No. LS–98–09]

RIN 0581–AB69

Regulations Governing the Certification of Sanitary Design and Fabrication of Equipment Used in the Processing of Livestock and Poultry Products

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Agricultural Marketing Service (AMS) has developed a voluntary, user-fee-funded program under the provisions of the Agricultural Marketing Act of 1946 to inspect and certify equipment and utensils used to process livestock and poultry products. Livestock and poultry processing equipment and utensils inspected and certified by AMS to voluntary consensus standards for sanitary design will provide a third party assurance that they meet minimum requirements for cleanability, suitability of materials used in construction, durability and inspectability.

EFFECTIVE DATE: January 8, 2001.

FOR FURTHER INFORMATION CONTACT: Barry Carpenter, Deputy Administrator, Livestock and Seed Program, by telephone at (202) 720–5705 or by Fax at (202) 720–3499.

SUPPLEMENTARY INFORMATION: The information that follows has been divided into three sections. The first one provides background information including a summary of the history of this rulemaking process. The second section provides a summary of the comments received in response to the proposed rule published in the **Federal Register** on June 6, 2000, and the Agency's responses to these comments including changes made in this final rule as a result of the comments. The last section provides the impact analysis section that addresses various requirements including the Regulatory Flexibility Act, the Paperwork Reduction Act, Civil Rights Review, and the relevant Executive Orders.

I. Background

Provisions of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001, (Pub. L. 106–387, sec. 729) require AMS to develop a voluntary, user-fee-funded program to inspect and certify equipment and utensils used to process livestock and poultry products. Prior to this amendment, similar language appeared in appropriations acts for fiscal year 1999 (Pub. L. 105–277, sec. 747) and fiscal year 2000 (Pub. L. 106–78, sec. 734). The program will be conducted under the provisions of the Agricultural Marketing Act (AMA) of 1946 (7 U.S.C. 1621 *et seq.*). From 1975 to 1997, a similar function was carried out by USDA on a mandatory prior approval basis by USDA's Food Safety and Inspection Service (FSIS) as a prerequisite for equipment use in federally inspected meat and poultry packing and processing establishments. The FSIS Equipment Branch formally evaluated equipment and utensils proposed by manufacturers or suppliers before they could be used in official establishments to assure they could be maintained in a sanitary condition. The program focused on identifying and correcting problems during the initial development of equipment and utensils.

FSIS's acceptance of new, modified, or reconditioned equipment and utensils for use in federally inspected meat and poultry establishments was a two-step process. First, FSIS Equipment Branch personnel evaluated the design and construction of equipment by reviewing assembly-type drawings and corresponding parts and material lists submitted to the Branch by the equipment manufacturer. Then, if necessary, FSIS inspectors reviewed the in-establishment operation of the equipment and reported their findings to the Equipment Branch. Commercially available equipment was accepted and listed in an FSIS reference guide, ''Accepted Meat and Poultry Equipment.'' Once equipment was listed in this reference as acceptable, no further approval was needed on an establishment basis.

FSIS continues to ensure that equipment and utensils used in federally inspected facilities are of such material and construction as will facilitate their thorough cleaning and operational cleanliness, and not adulterate edible product. Also, FSIS still requires that equipment and utensils used in federally inspected establishments are constructed, maintained, and used in a manner that does not interfere with inspection. However, in an effort to remove ''command and control'' regulations that were contrary to FSIS' commitment to the Hazard Analysis and Critical Control Point approach to Federal meat inspection, and to provide federally inspected establishments with the flexibility to use equipment and utensils designed in the manner they deem to best maintain a sanitary environment for food production without having to seek prior approval, FSIS discontinued the mandatory prior approval program for equipment and utensils on September 24, 1997 (62 FR 45016).

At the time FSIS announced that it was discontinuing its prior approval program, equipment and utensil manufacturers and processors of livestock and poultry products expressed their desire to either continue the FSIS program or develop a new program through AMS on a voluntary, user-fee-funded basis to inspect and certify equipment and utensils used to process livestock and poultry products to a sanitary standard. Subsequently, provisions of the fiscal year 1999 appropriations required development of such a program by the Secretary of Agriculture under the authority AMA of 1946.

Accordingly, on July 16, 1999, AMS published in the **Federal Register** (64 FR 38315) an advance notice of proposed rulemaking (ANPRM) and notice of public meeting to assist the Agency in the development of a complete inspection and certification program for equipment and utensils used to process livestock and poultry products.

Through the ANPRM and the public meeting, AMS sought information which would enable the Agency to develop an efficient and cost-effective program for inspecting and certifying equipment and utensils used to process livestock and poultry products. Specifically, AMS requested comments concerning: initiatives underway in the industry to develop a voluntary, consensus sanitary standard for the design and manufacture of equipment and utensils used to process livestock and poultry products; the validity and usability of standards presented to AMS for consideration for adoption; criteria to be used by AMS to select a sanitary standard; and any other information which would aid AMS in administering the program.

The ANPRM solicited comments on the issue for a 60-day period ending September 14, 1999. The public meeting was held on August 10, 1999, in Room 107–A at the USDA Jamie L. Whitten Building, 12th and Jefferson Drive, SW., Washington, DC.

To assist interested parties in obtaining information on the proposed program and in reviewing comments as AMS received them, the Agency launched a website at www.ams.usda.gov/lsg/equip.htm. Contained on this website were electronic versions of the AMS press releases related to the development of

the program, the ANPRM, complete transcripts of the August 10, 1999, public meeting, and all comments received.

The public meeting was attended by 42 representatives of the meat and poultry packing and processing industry, equipment and utensil manufacturing industry, trade and professional associations, standards developers, and other interested parties. Twelve individuals provided prepared remarks at the meeting. AMS received 51 comments during the comment period for the ANPRM.

On June 6, 2000, AMS published in the **Federal Register** (65 FR 35857), a proposed rule which responded to the ANPRM comments and solicited additional public comment. AMS received 100 comments during the comment period which ended August 7, 2000. The regulatory text of this final rule incorporates changes made in response to these comments and upon further review by AMS.

II. Comments and Responses

General Program Comments

Support for Program

Summary of Comments: Forty-one commenters expressed general support of the development of the program as presented in the proposed rule which included the standards developed by the NSF/3–A Joint Committee on Food Processing Equipment, the voluntary aspects of the service, and the use of Federal employees to provide the service. Thirty-three of these commenters specifically supported AMS as the certifying agency.

Agency Response: AMS has considered these comments in support of the program as it has contemplated changes from the proposed rule to this final rule.

Program Would Become Mandatory Requirement

Summary of Comments: Three commenters expressed concern that this program would become a ''de-facto'' mandatory requirement and that AMS should clearly state in the final rule that equipment manufacturers remain free to obtain other third party certifications or can ''self-certify'' that equipment is sanitarily designed and manufactured.

Agency Response: Throughout the development of these regulations and this program, AMS has maintained that the service to be implemented is voluntary and user-fee-funded. Accordingly, no equipment fabricator or user is required to participate in this program. Private certification providers can propose and offer other services to the livestock and poultry industries without restriction by these regulations. Therefore, equipment fabricators and users may use whatever means they desire, including ''self certification'', as suggested by commenters, to market or represent their products.

Comments Referring to AMS Providing the Inspection and Certification Service

Competition With the Private Sector

Summary of Comments: Five commenters generally opposed AMS providing the certification service because of concerns over public-private competition. One commenter also asserted that the Office of Management and Budget (OMB), Circular A–76 requires Federal agencies to use private sector services rather than offer duplicative services.

Agency Response: The comments received during the comment periods for the both ANPRM and the proposed rule indicate a clear desire by the livestock and poultry industry that this voluntary certification service be provided by AMS using government employees. These final regulations establish a voluntary, third-party evaluation service administered by AMS which is consistent with other, similar services provided by AMS for the inspection and grading of agricultural products, for laboratory services, for the evaluation of the sanitary design of equipment used in the dairy industry, and for the display of official identification marks. As such, no equipment fabricator or user is required to participate in this AMS service and equipment manufacturers and other users may choose any other voluntary, private certification service available to them. Furthermore, the regulations do not prevent, exclude or limit any private organization from independently offering a certification service of their own design to the livestock and poultry industry. With regard to concerns over the regulation's conformance with OMB Circular A–76, it is our view that this rule is consistent with the provisions of the Circular.

Effect of Program on Private Certification Providers

Summary of Comments: One commenter stated that AMS failed to consider the potential effects of the regulation upon private certification providers.

Agency Response: AMS did consider potential effects upon third parties. The service to be implemented by AMS is voluntary and user-fee-funded. As already stated, no equipment fabricator or user is required to participate in this program. Private certification providers may offer their services to the livestock and poultry industries without restriction by these regulations. Therefore, equipment fabricators and users may use whatever means they desire to demonstrate that their products are suitable for use.

Reexamine Alternatives to Proposed Program

Summary of Comments: One commenter asked AMS to reexamine alternatives under the agricultural appropriations act considering programs already implemented or publicly contemplated by AMS and offer an accreditation service for conformity assessment organizations in lieu of a certification service.

Agency Response: The Act provides that USDA develop a voluntary, user-fee-funded program to inspect and certify equipment used to process livestock and poultry products. Accordingly, the Agency examined alternatives, including the alternative suggested by the commenter. Additionally, AMS evaluated comments received in response to the ANPRM and the proposed rule as the alternatives were considered. The alternative option to develop a third-party certifier accreditation service was evaluated and rejected by AMS. The statutory language provides that the Secretary inspect and certify agricultural processing equipment. Further, a significant number of comments during the comment periods for the ANPRM and proposed rule which supported an AMS provided service staffed by Federal employees to conduct the evaluations.

Conformance of Program to ISO and ANSI Standards for Third Party Certification Bodies

Summary of Comments: Two commenters stated the proposed program did not conform to ISO or American National Standards Institute (ANSI) provisions or standards for third party certification bodies.

Agency Response: It has never been the objective or intent that the certification service provided by AMS would conform to ISO or ANSI provisions or standards for third party certification bodies. AMS intends to operate this program consistent with other voluntary, user-fee-funded inspection and certification services already provided by the Agency. AMS believes that this decision is consistent with the intent of Congress and the expectation of equipment manufacturers and meat and poultry processors who requested AMS develop the service.

Continued Compliance with NSF/3–A Standards

Summary of Comments: Two commenters stated that the proposed program did not provide for continued compliance with the NSF/3–A Standard and that the regulations need to offer interested parties the opportunity to question the appropriateness of an AMS certification of compliance. Additionally, one commenter asked what would happen to those manufacturers who do not report a change in the design of their equipment to AMS, and how would AMS verify if a change had occurred and was not reported.

Agency Response: After a review of the proposed regulations, AMS believes these comments have merit. Accordingly, § 54.1019 has been modified to require a manufacturer of any equipment or utensil which has been issued a report or certification of compliance to resubmit for evaluation any change in materials of construction, design, or fabrication which may impair the cleanability or hygienic design of the equipment or utensil. Similarly, AMS encourages interested parties to contact AMS if they have any questions regarding the appropriateness of an AMS certification of compliance. AMS can use this feedback as a basis for initiating a review to ensure that equipment marketed as certified through this program comply with the standards.

Recertification of Equipment

Summary of Comments: Seventy-two commenters requested AMS clarify or streamline the process for recertification of equipment. The commenters expressed confusion as to AMS' intent behind the wording used in the proposal stating that recertification by AMS was required after ''any'' change to the design was made. Commenters generally favored AMS only requiring recertification of equipment when a change of design is made that may affect the hygienic, cleanliness, or sanitary aspects of the equipment.

Agency Response: AMS agrees and has revised § 54.1019 in these regulations to clarify that only changes which impair the cleanability or hygienic design of the equipment or utensil need to be submitted for recertification.

Independent Audits

Summary of Comments: One commenter stated that the program did not provide for independent audits of the manufacturing facility.

Agency Response: The regulations do not provide for such audits as such audits are not intended to be a part of this service. AMS believes a requirement in these regulations for independent audits of the equipment or utensil manufacturers' facilities is not necessary. The addition of an AMS audit requirement of the manufacturer's facilities would substantially increase the cost of this voluntary program and the Agency believes the marginal benefit of such audits would be unwarranted. Additionally, the FSIS inspection program continues to be responsible for ensuring that equipment and utensils used in federally inspected facilities are of such material and construction as will facilitate their through cleaning and operational cleanliness, and not adulterate edible product. AMS believes the service to be provided by these regulations, particularly those in §§ 54.1019, contain sufficient internal controls to protect the integrity of its evaluations and certifications.

Requiring Samples, Material Lists and On-site Audits

Summary of Comments: One commenter objected to the program not requiring examination of samples, materials lists, or on-site audits. Three additional commenters requested clarification on the issue of when an on-site audit is required.

Agency Response: In order to allow for the greatest flexibility for applicants to apply for this service, AMS does not require blueprints, samples, and materials list be submitted with the application for all pieces of equipment and utensils. However, if sufficient information is unavailable for AMS to accurately evaluate the design of a specific piece of equipment or utensil, which could include the materials used in construction, a report or certification of acceptance will not be granted until such information that is required to perform the inspection is provided.

With respect to on-site audits, the evaluation and certification process includes the fabrication of the equipment or utensil. The only means available to AMS to accurately determine that acceptable fabrication techniques have been accomplished is to evaluate the completed piece of equipment or utensil. Depending upon the size and complexity of the equipment or utensil, this determination can only be accomplished with an on-site evaluation. Once a report or certificate of acceptance has been issued, additional on-site evaluations would be necessary only if the fabricator modified the design and requests a recertification under the provisions of § 54.1019. As appropriate to the review and evaluation process, AMS will conduct on-site reviews of the actual equipment at the point of fabrication or where installed. Section 54.1014 provide the regulatory language outlining the requirements for accessability of the equipment for evaluation.

Because AMS believes that blueprints, material lists and on-site audits will be required in virtually every instance envisioned by the Agency, the cost burden estimates for this program put forward in the Impact Analysis section of this rule assume all applicants will submit such documentation and will receive an on-site audit.

Model Lines

Summary of Comments: Ten commenters requested clarification of how AMS would process equipment which is part of a model line. Specifically, they requested clarification as to whether each member of the model line needed to be submitted for evaluation and certification.

Agency Response: AMS agrees that a clarification is needed. Accordingly, § 54.1006 has been modified by adding the wording, ''Equipment or utensils having an identical design, materials of construction, and fabrication, except for scaling up or down in size, may be submitted for evaluation as a model line or series.''

Four Year Certification Review

Summary of Comments: Three commenters objected to the requirement that certification must be reviewed every 4 years.

Agency Response: AMS disagrees. Based on experience, AMS believes equipment design and fabrication change frequently to meet the demands and needs of the equipment users. Section 54.1019 provides the requirements for these changes to be accommodated within the evaluation and certification process. For those types of equipment or utensil which change infrequently or not at all, the regulations provide for a simple procedure whereby the fabricator can state that no changes in the design or fabrication have occurred. AMS continues to support the need for these provisions as program integrity safeguards that the certifications issued by AMS are valid and that the four year recertification cycle is appropriate for AMS needs while not being overly restrictive to the livestock and poultry industries.

Comments Referring to the Selection of Standards That AMS Will Inspect and Certify Equipment To

Support for Adoption of NSF/3–A Standards

Summary of Comments: Twenty-two commenters supported the adoption of the standards developed by the NSF/3–A Joint Committee on Food Processing Equipment.

Agency Response: AMS has adopted these standards as the basis of this certification program.

Incorporation of NSF/3–A Standards

Summary of Comments: Sixty-nine commenters stated opposition to the way AMS incorporated the NSF/3–A standard in the proposed regulations. Commenters requested any changes to the standards be made through notice and comment in the **Federal Register**. One of the commenters stated AMS failed to follow OMB Circular A–119 made in the proposed rule.

Agency Response: As stated in the proposed rule, AMS will inspect and certify equipment and utensils to standards developed by the NSF/3–A Joint Committee on Food Processing Equipment. NSF is an ANSI *Designated Audited Certifier.* As such, NSF follows all ANSI procedures for standards development and the final published standards will be ANSI/NSF/3–A standards consistent with the provisions of OMB Circular A–119. AMS believes that these ANSI procedures provide for the required participation by all interested parties during all phases of the standards development process to ensure all points of view or concerns are considered before publication of the final standard. However, apart from the ANSI procedures for standards development, AMS encourages public comment on all of its services, and the standards the Agency uses as the basis of its services, including this program. To ensure that public comment is received prior to changes in the standards AMS uses, AMS will provide notice of pending changes in the standards to encourage interested parties to provide AMS with feedback and so they may also comment directly to the NSF/3–A Joint Committee.

Enforcement of the Worker Safety Provisions of the NSF/3–A Standards

Summary of Comments: Seventy-two commenters requested the program not enforce the worker safety provisions of the NSF/3–A standards adopted.

Agency Response: The scope of the NSF/3–A standards apply only to the hygienic requirements of the equipment or utensil design and had not intended to evaluate or comment on worker or occupational safety issues. Similar comments were also made to the NSF/3–A Joint Committee. In August 2000, the Joint Committee published NSF/3–A 14159–1, Draft 7.0 which included modified wording to delete the references to worker and occupational safety from application to livestock and poultry processing equipment and utensils. In view of the changes to the standards effected by the NSF/3–A Joint Committee, AMS believes the concerns raised by the commenters has been resolved and no additional action is needed by AMS.

Opposition to Use of Draft Standards

Summary of Comments: Two commenters objected to the use of the NSF/3–A standard because it is a draft standard.

Agency Response: At the time of the publication of the proposed rule the NSF/3–A standard was a draft standard, however the final ANSI/NSF/3–A standard has now been published and accepted as an American National Standard.

AMS Proposing One or Many Standards

Summary of Comments: One commenter was confused whether AMS was proposing one standard or many standards.

Agency Response: AMS will inspect and certify equipment and utensils to standards developed by the NSF/3–A Joint Committee on Food Processing Equipment. This Joint Committee will develop a wide-range of standards dealing with the hygienic design of equipment. As already stated, one standard has been completed by the Joint Committee and the committee is in the process of developing additional consensus standards. It is the intent of AMS to inspect and certify equipment and utensils to all standards finalized by the Joint Committee that are appropriate to the livestock and poultry industries. As standards are developed, this may result in the application of multiple standards by AMS to the appropriate pieces of equipment and utensils, as well as to the appropriate segments of the industry.

AMS Should Develop Its Own Standards

Summary of Comments: One commenter stated that they would have preferred that AMS write its own standards.

Agency Response: AMS disagrees. As already stated, AMS will inspect and certify equipment and utensils to standards developed by the NSF/3–A Joint Committee on Food Processing Equipment. AMS does not believe that the development of a new AMS standards would improve the service or provide users with any benefits.

Use of ISO Standards

Summary of Comments: One commenter recommended that any third party certifier should use International Organization for Standardization (ISO) standards.

Agency Response: The primary purpose of the regulations is to provide a third party certification that equipment meet specified standards. The service developed by AMS is intended to meet the needs expressed by the domestic livestock and poultry industries for a third party evaluation of the sanitary design of processing equipment according to specified standards. However, during development of the service, AMS did evaluate and consider international harmonization and compatibility with appropriate ISO standards. The standards developed by the NSF/3–A Joint Committee on Food Processing Equipment, which will be used by AMS, are based on the corresponding ISO standard, ISO/DIS 14159:1997 Safety of Machinery—Hygiene requirements for the design of machinery.

Representation of Manufacturers in NSF/3–A Standards Development Process

Summary of Comments: Two commenters objected to the use of the NSF/3–A standards because ''manufacturers were not represented''.

Agency Response: Equipment manufacturers are represented on the Joint Committee and the technical working groups. Further, the ANSI procedures followed by the Joint Committee for the development of standards requires that all interested parties be included in the development process.

Support for Other Standards

Summary of Comments: One commenter requested AMS adopt the ANSI/UL 2128—Meat and Poultry Plant Equipment Standard developed by the Underwriters Laboratories, Inc., instead of the NSF/3–A standard because the ANSI/UL 2128 standard is the American National Standard.

Agency Response: Since publication of the proposed rule, the NSF/3–A Joint Committee has now finalized their deliberation and published the draft standard that was proposed in final form. Accordingly, the NSF/3–A standard is now an American National Standard.

Suggested Revisions to NSF/3–A Standards

Summary of Comments: Thirteen commenters provided specific revisions that they would like made to the hygienic portions of the NSF/3–A draft standards.

Agency Response: AMS appreciates this feedback and will use it as it evaluates revisions that may need to be made to the NSF/3–A standards. AMS also recommends the commenters direct their specific revision changes to the NSF/3–A Joint Committee, NSF International, P. O. Box 130140, 789 N. Dixboro Rd., Ann Arbor, MI 48105.

As already stated, AMS encourages public comment on all of its services, and the standards the Agency uses as the basis of its services, including this program. To ensure that public comment is received prior to changes in the standards AMS uses, AMS will provide notice of pending changes in the standards to encourage interested parties to provide AMS with feedback and so they may also comment directly to the NSF/3–A Joint Committee.

Comments Referring to Administrative Issues

Grandfathering of Equipment Approved Under the Former FSIS Program

Summary of Comments: Two commenters requested that equipment approved under the former FSIS prior-approval program be ''grandfathered'' under this program.

Agency Response: AMS disagrees. The standards applicable under the two programs are different. It would be inappropriate for AMS to ''grandfather'' equipment that did not meet the standards proposed under this service that would then compete in the market place with equipment fabricators complying with the new standards.

AMS Work With Industry Associations

Summary of Comments: One commenter requested we inform the industry associations about what we are doing.

Agency Response: AMS agrees. AMS has participated in a number of informational meetings with all of the major industry trade associations whose members use AMS programs and services.

Keep Program Simple and Straightforward

Summary of Comments: One commenter requested we keep the program as ''simple and straightforward'' as possible.

Agency Response: AMS agrees. It is the goal of AMS in these regulations to provide a voluntary, user-fee-funded evaluation and certification program that meets the needs of the livestock and poultry industries, and is carried out in a manner as simple, straightforward, efficiently and cost effective as possible.

Marketing Claims

Summary of Comments: Nine commenters expressed concern over language in the proposed rule restricting the use of marketing claims on promotional literature for equipment not approved by this program. Additionally, commenters requested that approval letters from the former FSIS prior-approval program be allowed to be used and that such equipment be allowed to be marketed with the claim ''USDA accepted equipment'' and ''USDA approved.''

Agency Response: AMS disagrees. The standards and procedures provided for in these regulations are different than those implemented by the FSIS prior-approval program. As such, it would be unfair to participants in the this new program to have to compete with claims of manufacturers sanctioned under the former FSIS program which have not participated in this new AMS service. FSIS discontinued the mandatory prior approval program for equipment and utensils on September 24, 1997 (62 FR 45016). Since that time, there has been no procedure available to assure that the equipment or utensils covered by letters issued during the former FSIS program accurately represent the current equipment design or that such equipment even still meet current FSIS requirements.

Program Budgeting and Appropriations by Congress

Summary of Comments: One commenter stated their belief that the new service would be subject to congressional budgeting and appropriations.

Agency Response: The commenter is not correct. This service is fully user-fee supported.

AMS Staffing Levels and Certification Turnaround Times

Summary of Comments: Four commenters expressed concern over AMS staffing levels and turnaround times on certifications. Two of the commenters specifically asked that AMS include a maximum certification turnaround time in the regulations (30 and 60 days).

Agency Response: AMS will staff the program with sufficient personnel to accomplish the goals of the program using the best estimates available to AMS while still operating the program in an efficient and cost effective manner. AMS disagrees with the suggestion of commenters to include a maximum turnaround time in the regulations. Due to the complexity and sophistication of many of the designs eligible for evaluation and certification, turnaround time restrictions could be unrealistic and ultimately detrimental to the evaluation process.

Rejections of Applications

Summary of Comments: One commenter objected to AMS being able to reject an application based on ''administrative reasons such as the non-availability of personnel to perform the service.''

Agency Response: AMS disagrees. While AMS intends to provide service to applicants consistent with this subpart, there may be instances where such service may not be provided. Accordingly, the provision will remain unchanged.

Acceptance of Program by FSIS

Summary of Comments: One commenter requested AMS work to ensure this program is accepted by FSIS.

Agency Response: AMS has worked to ensure FSIS is fully aware of the services being developed by AMS. Additionally, AMS has informed FSIS of our availability to provide information about this service to their management or employees.

Third-party Appeal of Certification

Summary of Comments: One commenter requested that a section be added to the final rule allowing for users or other third-parties to question AMS certifications.

Agency Response: As already stated, AMS encourages interested parties to contact AMS if they have any questions regarding the appropriateness of an AMS certification of compliance. AMS can use this feedback as a basis for initiating a review to ensure that equipment marketed as certified through this program comply with the standards. The Agency believes this addresses the concern of the commenter sufficiently without the need for the insertion of a new section in the regulations. Accordingly, the regulations will remain unchanged.

Concurrent Reviews for Dairy and Meat and Poultry Equipment

Summary of Comments: One commenter requested that to improve efficiency, dairy and meat and poultry equipment reviews be done concurrently.

Agency Response: Although these regulations do not specifically provide for a ''concurrent'' review of equipment to be accepted for use under both this and the dairy equipment acceptance program, reviews will be conducted concurrently to all applicable standards upon the request of an applicant using the joint form used for both programs, DA–162, Equipment Review Request.

AMS Accepted Equipment Symbol Confusing

Summary of Comments: One commenter objected to the AMS symbol as confusing and leading observers to believe that the equipment bearing the symbol has the endorsement of FSIS.

Agency Response: AMS disagrees. These regulations are intended to meet the needs expressed by the domestic livestock and poultry industries for a third party evaluation of the sanitary design of processing equipment according to specified standards. These regulations and the services they provide for do not obligate or require any action on the part of FSIS. AMS believes these regulations can be used by the livestock and poultry industries to demonstrate they have had a third party evaluation of the hygienic design and fabrication of processing equipment according to specified standards. The symbol clearly references only AMS as the agency within USDA certifying acceptance. There is no reference, intended or implied, in these regulations of FSIS sanction of the symbol or the acceptance it represents. FSIS regulations specifically identify their responsibility for ensuring all Federally inspected meat and poultry establishments produce safe and wholesome products, regardless of whether the equipment and utensils used to process the products were certified by AMS under the provisions of this regulation.

Size and Format of AMS Accepted Equipment Symbol

Summary of Comments: Four commenters expressed concern over the size and format of the USDA ''Accepted Equipment'' symbol.

Agency Response: AMS agrees that the regulations were not sufficiently clear on the intended size of the symbol. Section 54.1018 has been revised to include subsection (c) recommending at least a 3/4 by 3/4 inch size for the official AMS symbol, but also allowing for smaller sizes to be used provided they are sufficiently large to be identifiable and legible. Accordingly, symbols of varying size could be used to be compatible with the use and location of the symbol on either the equipment or promotional materials. The use of the official AMS symbol for this program is consistent with the use of other official identification marks used within other AMS programs.

Comments Referring to Rulemaking Issues

Extension of Comment Period Accompanying the Proposed Rule

Summary of Comments: One commenter requested the comment period be extended.

Agency Response: AMS disagrees. The 60 day comment period which accompanied the ANPRM and the 60 day comment period which accompanied the proposed rule were sufficient to obtain the public comment required to develop the program.

Implement Program on a Trial Basis

Summary of Comments: One commenter requested the program be implemented as a 3-year pilot program.

Agency Response: AMS disagrees. Because this is a voluntary, user-fee-funded service there is no benefit to the program being implemented on a trial basis.

III. Impact Analysis

Executive Order 12866 and the Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), AMS has considered the economic impact of this proposed rule on small entities. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such action so that small businesses would not be disproportionally burdened. Accordingly, we have prepared this regulatory flexibility analysis.

Development of this program is required by the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001, (Pub. L. 106–387, sec. 729). The program will be conducted under the provisions of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*).

AMS is establishing these regulations to conduct a voluntary, user-fee-funded inspection and certification program for equipment and utensils that are used to process livestock and poultry products. Under this proposed program, manufacturers of new, modified, or reconditioned equipment and utensils designed to process livestock and poultry products who want to have the equipment and utensils they manufacture officially inspected and accepted by AMS as meeting the NSF/3–A standards which outline minimum requirements for cleanability, suitability of materials used in construction, inspectability and durability would apply to AMS.

Under this equipment and utensil acceptance program, equipment and utensil manufacturers seeking AMS acceptance and certification may apply to AMS for an evaluation of their equipment and utensils. Although AMS does not require the drawings, blueprints and a material list for all pieces of equipment or utensils upon application, such blueprints and lists must be submitted as will facilitate the inspection and certification process. Additionally, some equipment and utensils will require AMS to conduct an on-site review at the point of fabrication or where installed and operating in an establishment to fully evaluate the design and construction and execute final acceptance.

To maintain acceptance and certification, these regulations require any manufacturer whose equipment or utensil has been accepted to resubmit the design and fabrication details of the accepted equipment or utensils whenever a change of design or fabrication which may impair the cleanability or hygienic design of the equipment or utensil occurs. Barring changes in equipment or utensil design and fabrication, acceptance is granted for a four year period. When equipment or utensil acceptance nears expiration at the end of the four year period, manufacturers may send a letter stating that no design changes have been made to receive an additional four year acceptance renewal.

This action will benefit manufacturers of equipment and utensils used for processing meat and poultry products and the purchasers of such equipment and utensils by providing AMS certification that the equipment and utensils meet the minimum requirements of voluntary consensus standards for sanitary design. Acceptance by AMS will provide manufacturers and buyers assurance that equipment and utensils can be cleaned, are constructed of suitable materials, are durable, and can be inspected.

This equipment and utensil inspection and certification program affects manufacturers or other vendors of equipment and utensils. The

equipment and utensil manufacturers range in size from small to large concerns. According to the Standard Industrial Classification (SIC) (13 CFR 121.201) which are used by the Small Business Administration to identify small businesses, a small business equipment and utensil manufacturer is defined as a firm with less than 500 employees (SIC Division D. Major Group 20). According to the most complete data available to AMS, it is estimated that there are about 2000 equipment and utensil manufacturers, about 90 percent of these can be classified as small entities.

Previously, FSIS maintained a mandatory prior approval program for equipment and utensil inspection as a prerequisite for use in Federally inspected meat and poultry packing and processing establishments that affected these same entities. Under FSIS' former mandatory prior approval program for equipment, an estimated 2,500 applications for equipment approval were received each year. Evaluation and certification of equipment and utensils is based on the complexity and sophistication of the design and fabrication of the equipment or utensil being evaluated.

The paperwork burden that may be imposed on equipment and utensil manufacturers by this proposed action is further discussed in the section entitled Paperwork Reduction Act that follows.

In addition, we have not identified any relevant Federal rules that are currently in effect that duplicate, overlap, or conflict with this rule. Further, as discussed below, this program will be operated by the AMS Dairy Programs using its relevant fee structure.

Provisions of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001, require AMS to develop a voluntary, user-fee-funded program to inspect and certify equipment and utensils used to process livestock and poultry products. Prior to this amendment, similar language appeared in the appropriations acts for fiscal year 1999 (Pub. L. 105–277, sec. 747) and fiscal year 2000 (Pub. L. 106–78, sec. 734). The program will be conducted under the provisions of the Agricultural Marketing Act (AMA) of 1946. Under the AMA of 1946, AMS is required to collect reasonable fees for providing official services provided under this proposed equipment and utensil certification program, to cover as nearly as practicable AMS costs for performing the service, including related administrative and supervisory costs. Since the procedures used to inspect and certify equipment and utensils used to process livestock and poultry products are similar to those used to inspect and certify dairy processing equipment, AMS has decided to charge the same hourly fees for inspecting and certifying equipment used to process livestock and poultry products. Inspection and certification services are based on the hourly rate for applicants who request services on an hourly basis and appear at 7 CFR Part 58 as published in the **Federal Register** at 62 FR 66258 on December 18, 1997. The current base hourly rate for such service is $56 per hour for service performed between 6 a.m. and 6 p.m. and $61.60 for service performed between 6 p.m. and 6 a.m., for the time required to perform the service calculated to the nearest 15-minute period, including the time required for preparation of certificates and reports and the travel time of the equipment review specialist in connection with the performance of the service. A minimum charge of one-half hour will be made for the service pursuant to each request or certificate issued. If an applicant requests that certification service be performed on a holiday, Saturday, or Sunday or in excess of each 8-hour shift Monday through Friday, the applicant would be charged such service at a rate of 1½ times the rate which would be applicable for such service if performed during normal working hours.

AMS estimates that the time required to review and accept an initial submission for simple designs would be 1 hour. For complex designs, AMS estimates that the time required to review and accept an initial submission would be 8 hours. Based on the proposed AMS base hourly fee for service of $56 per hour, an initial submission of assembly type drawings and corresponding parts and material lists should range from $56 to $448. However, the final cost for equipment or utensil inspection and certification would be contingent on a final on-site review of the equipment or utensil at the point of fabrication or under conditions of actual use. The cost of this on-site review would include associated travel and per diem costs in addition to the hourly fee for service. AMS estimates the average time to perform a on-site review for a piece of equipment or utensil to be 12 hours.

The cost for evaluation of equipment or utensils would depend on the complexity of design, location of the equipment or utensil to be evaluated on-site, and whether the manufacturer has provided resource materials that would facilitate inspection of the equipment or utensil by AMS to determine acceptance. AMS estimates the average total costs to process and in-plant review a piece of equipment or utensil to be $1,120 plus added travel costs for the required on-site review. Assuming all equipment and utensil manufacturers would use an AMS equipment and utensil certification program to the extent they used the FSIS program, it is estimated that the total cost to the industry under an AMS program would be about $2,800,000 plus travel costs for on-site reviews annually. Since approximately 90 percent of equipment and utensil manufacturers are small businesses, the estimated share of the total annual industry burden directly affecting small businesses would be $2,520,000.

As stated in the previous section pertaining to the comments received in response to the proposed rule and the Agency's responses to them, the Act provides that USDA develop a voluntary, user-fee-funded program to inspect and certify equipment used to process livestock and poultry products. Accordingly, the Agency examined alternatives in developing such a program, including an alternative that would have allowed AMS to accredit third-party certifiers to act as agents of AMS, as well as the alternative to allow equipment and utensil manufacturers to self certify their equipment to AMS standards.

AMS considered these alternatives as it evaluated comments received in response to the ANPRM and the proposed rule as the alternatives were considered. The alternative options were rejected by AMS. The statutory language provides that the Secretary inspect and certify agricultural processing equipment. Further, a significant number of comments during the comment periods for the ANPRM and proposed rule which supported an AMS provided service staffed by Federal employees to conduct the evaluations.

In assessing alternatives to the scheme provided for in these regulations, we believe that the provisions contained herein will best accomplish the purpose of the program and at the same time minimize any burden that might be placed upon affected parties.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform and is not intended to have a retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. Further, section 729 of the

Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001, (Pub. L. 106–387) states that the provision does not affect the authority of the Secretary to carry out the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*); the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this final rule.

Paperwork Reduction Act Requirements

The proposed rule (65 FR 35857) contained paperwork submission requirements that were subject to public comment and to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. Chapter 35). In accordance with 5 CFR Part 1320, we included the description of the reporting requirements and an estimate of the annual burden on manufacturers of equipment and utensils used to process livestock and poultry products. As identified in § 54.1004 of these final regulations, the Certification of Sanitary Design and Fabrication of Equipment Used in the Slaughter, Processing, and Packaging of Livestock and Poultry Products service would be administered by AMS. During the administration of the service, AMS will expand the use of existing forms currently used by AMS and approved by OMB under 7 CFR part 58, subpart A, Regulations Governing the Inspection and Grading of Manufactured or Processed Dairy Products. The Agency published a **Federal Register** Notice 65 FR 2370, dated January 14, 2000, that expanded the use of these forms and allowed for a 60-day comment period. Additionally, the proposed rule for this action published in the **Federal Register**, 65 FR 35857, dated June 6, 2000, solicited comments from all interested parties concerning the information collection requirements contained in this proposed rule. Comments were specifically invited on the following: (1) The accuracy of the agency's burden estimate of the proposed collection of information including the validity of the methodology and assumptions used; (2) ways to minimize the burden of the collection of information on those who would respond, including through the use of appropriate electronic collection methods; (3) whether the proposed collection of information is sufficient or necessary for the proper performance of the functions of the agency to perform this program; and (4) ways to enhance the quality, utility, and clarity of the information to be collected.

Of the one hundred comments received for the proposed rule only one comment referenced the Paperwork Reduction Act requirements. This one commenter stated AMS substantially underestimated the number of applications per respondent. The commenter based the comment on the history of their company's applications under the former FSIS prior approval program. The AMS published estimates are based on the expected average number of respondents. Any one applicant may exceed the number of applications submitted based on their voluntary participation in the service provided. However, AMS believes that the published average number of applications is accurate for the program and has not revised its estimates.

OMB Number: 0581–0126.

Expiration Date of Approval: August 31, 2003.

Abstract: The dairy grading program is a voluntary, user-fee-funded program. In order for a voluntary inspection program to perform satisfactorily with a minimum of confusion, there must be written requirements and rules for both Government and industry. The information collections are essential to carry out and administer the inspection and grading program. The information requested is used to identify the product offered for grading, to identify a request from an equipment manufacturer of equipment used in the dairy, meat or poultry industries for evaluation for sanitary design and construction, to identify and contact the party responsible for payment of the inspection, grading or equipment evaluation fee and expense, to identify applicants who wish to be authorized for the display of official identification on product packaging materials, equipment, utensils, or on descriptive or promotional materials.

The equipment and utensil inspection and certification proposed herein would use the forms described above in a program that would be conducted by AMS on a voluntary, fee-for-service basis. Manufacturers of new, modified, or reconditioned equipment and utensils designed to process livestock and poultry products who want to have the equipment or utensils they manufacture officially inspected and accepted by AMS as meeting the NSF/3-A standards which outline minimum requirements for cleanability, suitability of materials used in construction, inspectability and durability would apply to AMS.

For the purposes of the burden estimate, AMS estimated that the hourly wage for those submitting information would be $20 per hour. To have equipment and utensils accepted under this program, equipment and utensil manufacturers would submit an application to AMS requesting evaluation of equipment or utensils (Form DA–162). AMS estimates that of the 2000 livestock and poultry equipment and utensil manufacturers, AMS will receive approximately 2500 applications per year or, on average, 1.25 applications from each manufacturer. Form DA–162 requires 0.038 hours to complete. The total annual burden on the industry for this proposed collection of information would be 95 hours or $1,900 annually. Since AMS does not require the drawings, blueprints and a material list to be submitted, they have not been included in this burden estimate.

Manufacturers whose equipment or utensil receives AMS acceptance may, upon request, be issued an official certificate as proof that the equipment or utensil meets NSF/3-A standards and is therefore accepted. Since completion of this certificate is performed by AMS, it has also not been included in this burden estimate. Upon written application (Form DA–155 and Form DA–156), manufacturers of accepted equipment or utensils may receive permission to display the official mark of acceptance on equipment and utensils, or in promotional literature as illustrated in the regulatory text (Figure 1). Form DA–155 is a one-time application from each manufacturer and, therefore, has been estimated to only be sent by a respondent once in every four-year cycle of equipment and utensil approval. The estimate of the total annual burden of this collection of information is 10.5 hours or $210 annually. Form DA–156 is submitted by a manufacturer each time there is a request to use the symbol on a piece of equipment or utensil, or in promotional literature. AMS estimates that it would receive one request each year to use the symbol on equipment or utensils, or in promotional material for each piece of equipment or utensil accepted. Therefore, AMS estimates that the total annual burden for this collection of information would be 42.5 hours or $850 annually.

Manufacturers whose equipment or utensil does not meet the design and fabrication requirements of the NSF/3–A standards and does not receive acceptance by AMS may appeal AMS' determination. The manufacturers would make a request for appeal service with the Chief, Dairy Grading Branch by completing and submitting a request for service (Form DA–162) to have

equipment or utensils reevaluated. The appeal process is set forth in sections § 54.1020 through § 54.1027 of the proposed regulations. As the AMS Dairy Program has never received an appeal for service under its current equipment acceptance program, AMS has estimated that 1% of applicants will appeal service in this estimate of the burden of the collection of information. Accordingly, with 2500 applications per year and Form DA–162 requiring 0.038 hours to complete and an estimate of only 1 percent of applicants requiring an appeal, the total annual burden on the industry for this proposed collection of information would be 0.95 hours or $19 annually.

Any manufacturer whose equipment or utensil has been certified shall resubmit the design and fabrication details of the certified equipment or utensil whenever a change of design or fabrication has occurred. Certification of equipment or utensils that have not changed remains in effect for a period of four years. If no changes in equipment or utensil design or fabrication have occurred over the four year period since the last certification was made, manufacturers must submit a certificate of conformance signed by the chief engineering officer and chief executive officer of the company stating that no design changes have been made to receive certification renewal. AMS estimates that it would receive one such request every four years for each piece of equipment or utensil accepted. AMS estimates that the total annual burden for this collection of information would be 52 hours or $1,040 annually.

Collectively, AMS estimated that the total annual burden for the collection of information would be 200.95 hours or $4019 annually.

1. Equipment Review Request—Form DA–162

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.038 hours per response.

Respondents: Manufacturers of equipment and utensils used to process livestock and poultry products.

Estimated Number of Respondents: 2000.

Estimated Number of Responses per Respondent: 1.25.

Estimated Total Annual Burden on Respondents: 95 hours.

Total Cost: $1,900.

2. Application To Use official ID—Form DA–155

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.021 hours per response.

Estimated Number of Respondents: 2000.

Estimated Number of Responses per Respondent: 0.250.

Estimated Total Annual Burden on Respondents: 10.5 hours.

Total Cost: $210.

3. Request To Display Official ID—Form DA–156

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.017 hours per response.

Estimated Number of Respondents: 2000.

Estimated Number of Responses per Respondent: 1.25.

Estimated Total Annual Burden on Respondents: 42.5 hours.

Total Cost: $850.

4. Appeal—Equipment Review Request—Form DA–162

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.038 hours per response.

Respondents: Manufacturers of equipment and utensils used to process livestock and poultry products.

Estimated Number of Respondents: 2000.

Estimated Number of Responses per Respondent: 0.0125.

Estimated Total Annual Burden on Respondents: 0.95 hours.

Total Cost: $19.

5. Letter Requesting Renewal of Acceptance

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.083 hours per response.

Estimated Number of Respondents: 2000.

Estimated Number of Responses per Respondent: 0.313.

Estimated Total Annual Burden on Respondents: 52 hours.

Total Cost: $1,040.

Estimated Total Annual Burden on Respondents: 200.95 hours total or 0.1 hours per respondent.

Estimated Total Annual Costs: $4,019 or $2 per respondent.

It is found that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because this (1) is a voluntary, user-fee-funded program; (2) equipment manufacturers are aware of the provisions of this rule, which a 60-day comment period was provided for in the proposed rule; and (3) have already begun to request this service.

List of Subjects in 7 CFR Part 54

Food Grades and standards, Food labeling, Meat and meat products.

For the reasons set forth in the preamble 7 CFR Part 54 is amended as follows:

PART 54—MEATS, PREPARED MEATS, AND MEAT PRODUCTS (GRADING, CERTIFICATION, AND STANDARDS)

1. The authority citation for part 54 continues to read as follows:

Authority: 7 U.S.C. 1621–1627; Pub. L. 106–387, sec. 729.

2. In Part 54 a new Subpart C consisting of §§ 54.1001 through 54.1034 is added to read as follows.

Subpart C—Regulations Governing the Certification of Sanitary Design and Fabrication of Equipment Used in the Slaughter, Processing, and Packaging of Livestock and Poultry Products

Sec.

Subpart C—Regulations Governing the Certification of Sanitary Design and Fabrication of Equipment Used in the Slaughter, Processing, and Packaging of Livestock and Poultry Products

§ 54.1001 Meaning of words.

For the purposes of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand.

§ 54.1002 Terms defined.

Act. The Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*).

Administrator. The Administrator of the Agricultural Marketing Service (AMS), United States Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

Applicant. Any person who applies for service under the regulations in this subpart.

Branch. The Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service.

Chief. The Chief of the Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service, or the representative to whom authority has been delegated to act in the stead of the Chief.

Compliance. Conformity of a processing system, piece of processing equipment, or a utensil to identified standards.

Department. The United States Department of Agriculture.

Deputy Administrator. The Deputy Administrator of the Dairy Programs of the Agricultural Marketing Service or any officer or employee of the Dairy Programs to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated to act in the stead of the Deputy Administrator.

Design Review Specialist. An employee of the Branch who determines and certifies or otherwise evaluates the compliance of equipment or utensils under the regulations.

Design Evaluation and Certification Service. The service established and conducted under the regulations for the evaluation and certification or other identification of the compliance of equipment or utensils used for the slaughter, processing or packaging of livestock and poultry products (Referred to hereinafter as ''equipment'' or ''utensils'') with sanitary specifications or standards.

Fabricator. Commercial entity engaged in the manufacture or assembly of equipment or utensils.

Financially interested person. Any person having a financial interest in the equipment or utensils involved, including but not limited to the designer, fabricator, or user of the equipment or utensils.

Legal Holiday. Those days designated as legal public holidays in Title 5, United States Code, section 6103(a).

Person. Any individual, partnership, corporation, or other legal entity, or Government agency.

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, or otherwise manufacturing, and includes the packaging, canning, jarring, or otherwise enclosing in a container.

Program. The Dairy Programs of the Agricultural Marketing Service.

Standards. The most recent version of standards for equipment and utensils formulated by the NSF/3–A Joint Committee on Food Processing Equipment (Referred to hereinafter as ''NSF/3–A'').

The regulations. The regulations in this Subpart.

§ 54.1003 Designation of official certificates, memoranda, marks, and other identifications, for purposes of the Agricultural Marketing Act.

Subsection 203(h) of the Agricultural Marketing Act of 1946, as amended provides criminal penalties for various specified offenses relating to official certificates, memoranda, and marks or other identifications, issued or authorized under section 203 of said Act, and certain misrepresentations concerning the inspection or grading of agricultural products under said section. For the purposes of said subsection and the provisions in this subpart, the terms listed in paragraphs (a) through (c) of this section shall have the respective meanings specified:

(a) ''Official certificate'' means any form of certification, either written or printed, used under the regulations to certify with respect to the evaluation, review, condition, or acceptance of equipment or utensils (including the compliance of equipment or utensils with applicable standards).

(b) ''Official memorandum'' means any initial record of findings made by an authorized employee of the Dairy Grading Branch in the process of determining compliance, evaluating, or reviewing equipment or utensils pursuant to the regulations, any processing or in plant-operation report made by an authorized Dairy Grading Branch employee in connection with determining compliance, evaluating, or reviewing equipment or utensils under the regulations, and any report made by an authorized employee of the Dairy Grading Branch of any other services performed pursuant to the regulations.

(c) ''Official mark'' or ''other official identification'' means any form of mark or other identification, including those prescribed in § 54.1018; used under the regulations in marking any equipment or utensils or displayed as an indication that the equipment or utensils has been evaluated by AMS (including the compliance of the equipment or utensils with applicable standards).

§ 54.1004 Administration and implementation.

The Administrator designates the administration and implementation of the Certification of Sanitary Design and Fabrication of Equipment Used in the Processing of Livestock and Poultry Products service to the Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service. The Chief is charged with the administration, under the general supervision and direction of the Deputy Administrator, of the regulations and the Act insofar as they relate to equipment or utensils used to process livestock and poultry products.

§ 54.1005 Basis of service.

(a) Certification of Sanitary Design and Fabrication of Equipment Used in the Slaughter, Processing, and Packaging of Livestock and Poultry Products service shall be performed in accordance with the provisions of this subpart, the instructions and guidelines issued or approved by the Chief and the applicable standards developed by the NSF/3–A.

(b) Copies of standards developed by NSF/3–A that AMS will inspect and certify to are available, for a nominal fee, from NSF International at www.nsf.org or contact Techstreet, 310 Miller Avenue, Ann Arbor, MI 48103; Phone (800) 699–9277. Copies of all other instructions and guidelines can be obtained from, and copies of standards developed by NSF/3–A may be inspected at, the U.S. Department of Agriculture, Agricultural Marketing Service, Dairy Programs, Dairy Grading Branch; Room 2746–S; 1400

Independence Ave., SW., Washington, DC 20250–6456.

(c) All services provided in accordance with the regulations shall be rendered without discrimination on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

§ 54.1006 Kind of service.

Certification of Sanitary Design and Fabrication of Equipment Used in the Slaughter, Processing, and Packaging of Livestock and Poultry Products service under the regulations shall consist of the evaluation, certification and/or identification, upon request by the applicant, of the adherence of the design and fabrication of equipment and utensils to sanitary principles and criteria under applicable standards identified in this subpart. Equipment or utensils having an identical design, materials of construction, and fabrication, except for scaling up or down in size, may be submitted for evaluation as a model line or series. Determination as to equipment or utensils compliance with standards for materials of fabrication or method of fabrication may be based upon information received from the fabricator.

§ 54.1007 Availability of service.

Service under these regulations may be made available to the designers, fabricators, users, or other interested person or party, of the equipment or utensils. Subject to the provisions of this subpart, services shall be performed only when a qualified design review specialist is available, and when the location of the equipment or utensils, evaluation facilities and conditions, as determined by the Chief, are suitable for conducting such service.

§ 54.1008 How to obtain service.

(a) *Application.* Any person may apply to the Chief for service under the regulations with respect to equipment or utensils in which the applicant is financially interested. The application shall be made on a form approved by the Chief. In any case in which the service is intended to be furnished at an establishment not operated by the applicant, the applicant shall be responsible for obtaining approval for accessability of the equipment or utensil from the operator of such establishment and such approval shall constitute an authorization for any employees of the Department to enter the establishment for the purpose of performing their functions under the regulations. The application shall state:

(1) The name and address of the establishment at which service is desired;

(2) The name and post office address of the applicant;

(3) Identification of the party that will be responsible for payment of all services rendered in response to the request;

(4) The type of equipment or utensil presented for evaluation;

(5) The date(s) on which service is requested to be performed; and

(6) The signature of the applicant (or the signature and title of the applicant's representative) and date of the request.

(b) *Notice of eligibility for service.* The applicant for service will be notified whether the applicant's application is approved.

§ 54.1009 Order of furnishing service.

Service under the regulations shall be furnished to applicants, insofar as practicable and subject to the availability of a qualified design review specialist, in the order in which requests therefor are received, insofar as consistent with good management, efficiency and economy. Precedence will be given, when necessary, to requests made by any government agency and to requests for appeal service under § 54.1021.

§ 54.1010 When request for service deemed made.

A request for service under the regulations shall be deemed to be made when received by the Branch. Records showing the date and time of the request shall be maintained.

§ 54.1011 Withdrawal of application or request for service.

An application or a request for service under the regulations may be withdrawn by the applicant at any time before the application is approved or prior to performance of service. The applicant shall be responsible for payment, in accordance with § 54.1028 and § 54.1029, of any expenses already incurred by the Agricultural Marketing Service in connection therewith.

§ 54.1012 Authority of agent.

Proof of the authority of any person making an application or a request for service under the regulations on behalf of any other person may be required at the discretion of the Deputy Administrator or Chief or other employee receiving the application or request under § 54.1008.

§ 54.1013 When an application may be rejected.

(a) An application or a request for service may be denied by the design review specialist, with the concurrence of the Deputy Administrator or Chief when:

(1) For administrative reasons such as the non-availability of personnel to perform the service;

(2) The application or request relates to equipment or utensils which are not eligible for service under § 54.1006;

(3) The applicant fails to meet either the application requirements prescribed in this subpart or the conditions for receiving such service;

(4) The equipment or utensil is owned by, or located on the premises of, a person currently denied the benefits of the Act;

(5) The applicant has substantial financial ties to a person who is currently denied the benefits of the Act, or who has been adjudged, in an administrative or judicial proceeding, responsible in any way for a current denial of benefits of the Act to any other person.

(6) The applicant is currently denied services under the Act.

(7) Any fees billed to the applicant are not paid within 30 days; or

(8) The applicant has failed to comply with the Act or this subpart or with the instructions or guidelines issued hereunder.

(b) The Chief shall provide notice to an applicant whose application is rejected, and shall explain the reason(s) for the rejection. If such notification is made verbally, written confirmation may be provided.

§ 54.1014 Accessibility of equipment and utensils; access to establishments.

(a) The applicant shall cause equipment and utensils to be made easily accessible for examination and to be so placed, with adequate illumination to facilitate evaluation for compliance. The applicant shall furnish or make available any necessary tools; such as boroscope, profilometer, disassembly tools, ladders, radius gauges, and the like; necessary to complete the evaluation.

(b) Supervisors of USDA design review specialists responsible for maintaining uniformity and accuracy of service under the regulations shall have access to all parts of establishments covered by approved applications for service under the regulations, for the purpose of examining all equipment or utensils in the establishments which have been or are to be evaluated for compliance with standards or which bear any marks of compliance.

§ 54.1015 Official reports, forms, and certificates.

(a) *Report.* The design review specialist shall prepare, sign, and issue

a narrative report covering the observations, comments and recommendations based on the evaluation for conformance with standards of equipment and utensils as provided for in § 54.1005 and indicate the fees and other charges incurred for the services rendered.

(b) *Forms.* Form DA–161 is the official certificate for equipment or utensils evaluated and is accepted under the regulations. Issuance of this certificate is optional at the request of the applicant.

(c) *Distribution.* The original report and official certificate (if requested) shall be delivered or mailed to the applicant or other persons designated by the applicant. Other copies shall be forwarded as required by agency, program, and branch instructions. Additional copies will be furnished to any person financially interested in the equipment or utensil involved with the concurrence of the applicant and upon payment of fees, as provided in § 54.1028 and § 54.1029.

§ 54.1016 Advance information concerning service rendered.

Upon request of any applicant, all or any part of the contents of any report issued to the applicant under the regulations, or other notification concerning the determination of compliance of equipment or utensils for such applicant may be transmitted by facsimile transmission to the applicant, or to any person designated by the applicant at the applicant's expense.

§ 54.1017 Authority to use official identification.

The Chief may authorize an applicant or any persons designated by the applicant to use the official identification symbol to mark equipment or utensils, or for display in descriptive or promotional materials providing the equipment or utensils is evaluated pursuant to this subpart and found to be in compliance.

§ 54.1018 Form of official identification and approval for use.

(a) The official identification symbol approved for use on equipment, utensils, or descriptive or promotional materials shall appear in the form and design shown in Figure 1.

(b) The official identification symbol on equipment or utensils shall be displayed by etching or the placement of a non-removable sticker located in close proximity to the equipment identification plate.

(c) The official identification symbol is recommended to be at least 3/4 inch by 3/4 inch in size. Symbols which are smaller in size will be considered provided they are sufficiently large to be identifiable and legible.

(d) The official identification symbol shall not be used in descriptive and promotional materials without prior approval by the Chief. The official identification symbol, if used, on the descriptive or promotional materials shall be printed as part of the text or format.

(e) An applicant shall submit to the Chief of the Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service, U.S. Department of Agriculture, P.O. Box 96456, Washington, D.C. 20090–6456, an application, if one is not on file, requesting approval to use the official identification symbol on officially accepted equipment and in descriptive or promotional materials.

BILLING CODE 3410–02–P

Figure 1. Official identification symbol.

BILLING CODE 3410–02–C

§ 54.1019 Renewal of acceptance certification.

The manufacturer of any equipment or utensil which has been issued a report or certification stating acceptance of compliance shall resubmit the design and fabrication details of any change in materials of construction, design, or fabrication which may impair the cleanability or hygienic design of the equipment or utensil. If no change in materials of construction, design, or fabrication which may impair the cleanability or hygienic design of the equipment or utensil has occurred during the period of four years after the date of the most recent report stating acceptance of compliance or if no design or fabrication changes have been made, the applicant may submit a certificate of conformance signed by the chief engineering officer and the chief executive officer of the company stating that no design changes have been made to the specified equipment or utensil.

§ 54.1020 Appeal service; marking equipment or utensils on appeal; requirements for appeal; certain determinations not appealable.

(a) Appeal service is a re-evaluation of the compliance of a piece of equipment, portion of a piece of equipment, or utensil to design or fabrication criteria according to the standards prescribed by this subpart.

(b) Only the original applicant or their representative may request appeal service requesting a reevaluation of the original determination of the design and fabrication of the equipment or utensil for compliance with the standards specified in this subpart.

(c) Appeal service will not be furnished for:

(1) A piece of equipment, portion of a piece of equipment, or utensil which has been altered or has undergone a material change since the original service.

(2) For the purpose of obtaining an up-to-date report or certificate which does not involve a question as to the correctness of the original service for the piece of equipment, portion of a piece of equipment, or utensil.

§ 54.1021 Request for appeal service.

(a) Except as otherwise provided in § 54.1020, an applicant or their representative may request appeal service when the applicant or their representative disagree with the determination as to compliance with the standard of the piece of equipment, portion of a piece of equipment, or utensil as documented in the applicable report.

(b) A request for appeal service shall be filed with the Chief, directly or through the design review specialist who performed the original service. The request shall state the reasons for the disagreement with the original determination and may be accompanied by a copy of any previous certificate or report, or any other information which the applicant may have received regarding the piece of equipment, portion of a piece of equipment, or utensil at the time of the original service. Such request may be made orally (including by telephone) or in writing (including by facsimile transmission). If made orally, the Dairy Grading Branch employee receiving the request may require that it be confirmed in writing.

§ 54.1022 When request for appeal service may be withdrawn.

A request for appeal service may be withdrawn by the applicant at any time before the appeal service has been performed, upon payment of any expenses already incurred under the regulations by the Branch in connection therewith.

§ 54.1023 Denial or withdrawal of appeal service.

A request for appeal service may be rejected or such service may be otherwise denied to or withdrawn from any person in accordance with the procedure set forth in § 54.1013(a), if it appears that the person or product involved is not eligible for appeal service under § 54.1020, or that the identity of the piece of equipment, portion of a piece of equipment, or utensil has been lost; or for any of the causes set forth in § 54.1032.

§ 54.1024 Who shall perform appeal service.

Appeal service for equipment or utensils shall be performed by the Chief or a design review specialist designated by the Chief. No design review specialist may perform appeal service for any piece of equipment, portion of a piece of equipment or utensil for which the original design review specialist performed the initial evaluation service.

§ 54.1025 Appeal reports.

After appeal service has been performed for any piece of equipment, portion of a piece of equipment or utensils, an official report shall be prepared, signed, and issued referring specifically to the original report and stating the determination of the re-evaluation of compliance of the piece of equipment, portion of a piece of equipment or utensil.

§ 54.1026 Superseded reports.

The appeal report shall supersede the original report which, thereupon, shall become null and void for all or a portion of the report pertaining to the appeal service and shall not thereafter be deemed to show the compliance of the equipment or utensils described therein. However, the fees charged for the original service shall not be remitted to the applicant who filed the appeal.

§ 54.1027 Application of other regulations to appeal service.

The regulations in this subpart shall apply to appeal service except insofar as they are inapplicable.

§ 54.1028 Fees and other charges for service.

Fees and other charges equal as nearly as may be to the cost of the services rendered shall be assessed and collected from applicants in accordance with the provisions for Fees and Charges set forth in 7 CFR part 58, Subpart A, Regulations Governing the Inspection and Grading Services of Manufactured or Processed Dairy Products, sections §§ 58.38, 58.39, 58.41, 58.42, and 58.43, as appropriate.

§ 54.1029 Payment of fees and other charges.

Fees and other charges for service shall be paid upon receipt of billing for fees and other charges for service. The applicant shall remit by check, draft, or money order, made payable to the Agricultural Marketing Service, USDA, payment for the service in accordance with directions on the billing, and such fees and charges shall be paid in advance if required by the official design review specialist or other authorized official.

§ 54.1030 Identification.

All official design review specialists and supervisors shall have their Agricultural Marketing Service identification cards in their possession at all times while they are performing any function under the regulations and shall identify themselves by such cards upon request.

§ 54.1031 Errors in service.

When a design review specialist, supervisor, or other responsible employee of the Branch has evidence of inaccurate evaluation, or of incorrect certification or other incorrect determination or identification as to the compliance of a piece of equipment or utensil, such person shall report the matter to the Chief. The Chief will investigate the matter and, if deemed advisable, will report any material errors to the owner or the owner's agent. The Chief shall take appropriate action

to correct errors found in the determination of compliance of equipment or utensils, and the Chief shall take adequate measures to prevent the recurrence of such errors.

§ 54.1032 Denial or withdrawal of service.

(a)*(1) Bases for denial or withdrawal.* An application or a request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person who, or whose employee or agent in the scope of the person's employment or agency:

(i) Has wilfully made any misrepresentation or has committed any other fraudulent or deceptive practice in connection with any application or request for service under the regulations;

(ii) has given or attempted to give, as a loan or for any other purpose, any money, favor, or other thing of value, to any employee of the Department authorized to perform any function under the regulations;

(iii) has interfered with or obstructed, or attempted to interfere with or to obstruct, any employee of the Department in the performance of duties under the regulations by intimidation, threats, assaults, abuse, or any other improper means;

(iv) has knowingly falsely made, issued, altered, forged, or counterfeited any official certificate, memorandum, mark, or other identification;

(v) has knowingly uttered, published, or used as true any such falsely made, issued, altered, forged, or counterfeited certificate, memorandum, mark or identification;

(vi) has knowingly obtained or retained possession of any such falsely made, issued, altered, forged, or counterfeited certificate, memorandum, mark or identification, or of any equipment or utensil bearing any such falsely made, issued, altered, forged, or counterfeited mark or identification;

(vii) has applied the designation ''USDA Accepted Equipment'', ''AMS Accepted Equipment'', ''USDA Approved Equipment'', ''AMS Approved Equipment'', ''Approved By USDA'', ''Approved By AMS'', ''Accepted By USDA'', ''Accepted By AMS'', ''USDA Approved'', ''USDA Accepted'', ''AMS Approved'', ''AMS Accepted'', or any other variation of wording which states or implies official sanction by the United States Department of Agriculture by stamp, or brand directly on any equipment or utensil, or used as part of any promotional materials which has not been inspected and deemed in compliance with this subpart; or,

(viii) has in any manner not specified in this paragraph violated subsection 203(h) of the AMA: *Provided,* That paragraph (a)(1)(vi) of this section shall not be deemed to be violated if the person in possession of any item mentioned therein notifies the Deputy Administrator or Chief without such delay that such person has possession of such item and, in the case of an official identification, surrenders it to the Chief, and, in the case of any other item, surrenders it to the Deputy Administrator or Chief or destroys it or brings it into compliance with the regulations by obliterating or removing the violative features under supervision of the Deputy Administrator or Chief: *And provided further,* That paragraphs (a)(1) (ii) through (vii) of this section shall not be deemed to be violated by any act committed by any person prior to the making of an application of service under the regulations by the principal person. An application or a request for service may be rejected or the benefits of the service may be otherwise denied to, or withdrawn from, any person who operates an establishment for which such person has made application for service if, with the knowledge of such operator, any other person conducting any operations in such establishment has committed any of the offenses specified in paragraphs (a)(1) (i) through (vii) of this section after such application was made. Moreover, an application or a request for service made in the name of a person otherwise eligible for service under the regulations may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, such a person:

(A) In case the service is or would be performed at an establishment operated:

(*1*) By a corporation, partnership, or other person from whom the benefits of the service are currently being withheld under this paragraph; or

(*2*) By a corporation, partnership, or other person having an officer, director, partner, or substantial investor from whom the benefits of the service are currently being withheld and who has any authority with respect to the establishment where service is or would be performed; or

(B) In case the service is or would be performed with respect to any product in which any corporation, partnership, or other person within paragraph (a)(1)(viii)(A)(*1*) of this section has a contract or other financial interest.

(2) *Procedure.* All cases arising under this paragraph shall be conducted in accordance with the Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes set forth in 7 CFR §§ 1.130 through 1.151 and the Supplemental Rules of Practice in part 50, 7 CFR § 50.1 *et seq.*

(b) *Filing of records.* The final orders in formal proceedings under paragraph (a) of this section to deny or withdraw the service under the regulations (except orders required for good cause to be held confidential and not cited as precedents) and other records in such proceedings (except those required for good cause to be held confidential) shall be filed with the Hearing Clerk and shall be available for inspection by persons having a proper interest therein.

§ 54.1033 Confidential treatment.

Every design review specialist providing service under these regulations shall keep confidential all information secured and not disclose such information to any person except an authorized representative of the Department.

§ 54.1034 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

The following control number has been assigned to the information collection requirements in 7 CFR Part 54, Subpart C, by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

7 CFR section where requirements are described	Current OMB control No.
54.1008(a)	0581–0126
54.1017	0581–0126
54.1018(e)	0581–0126
54.1019	0581–0126
54.1020	0581–0126
54.1021	0581–0126

Dated: December 27, 2000.

Barry L. Carpenter,

Deputy Administrator, Livestock and Seed Program.

[FR Doc. 01–95 Filed 1–4–01; 8:45 am]

BILLING CODE 3410–02–P

Federal Register

Friday,

January 5, 2001

Part III

Environmental Protection Agency

40 CFR Part 745

Lead; Identification of Dangerous Levels of Lead; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 745

[OPPTS–62156H; FRL–6763–5]

RIN 2070–AC63

Lead; Identification of Dangerous Levels of Lead

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing a final regulation under section 403 of the Toxic Substances Control Act (TSCA), as amended by the Residential Lead-Based Paint Hazard Reduction Act of 1992, also known as ''Title X (ten),'' to establish standards for lead-based paint hazards in most pre-1978 housing and child-occupied facilities. This regulation supports the implementation of regulations already promulgated, and others under development, which deal with worker training and certification, lead hazard disclosure in real estate transactions, requirements for lead cleanup under State authorities, lead hazard evaluation and control in Federally-owned housing prior to sale and housing receiving Federal assistance, and U.S. Department of Housing and Urban Development (HUD) grants to local jurisdictions to perform lead hazard control. In addition, today's action also establishes, under authority of TSCA section 402, residential lead dust cleanup levels and amendments to dust and soil sampling requirements and, under authority of TSCA section 404, amendments to State program authorization requirements. By supporting implementation of the major provisions of Title X and by providing guidance to all owners and occupants of pre-1978 housing and child-occupied facilities, this regulation will help to prevent lead poisoning in children under the age of 6.

DATES: This final rule is effective on March 6, 2001. This rule shall be promulgated for purposes of judicial review at 1 p.m. eastern daylight time on February 5, 2001.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Director, Office of Program Management and Evaluation, Office of Pollution Prevention and Toxics (7401), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: 202–554–1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Dave Topping, National Program Chemicals Division (7404), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 260–7737; e-mail address: topping.dave@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you must comply with other Title X regulations that are affected by today's action. The following table identifies potentially affected categories and entities:

Category	Examples of Entities	NAICS or SIC codes	Effect of Regulation
Lead abatement professionals	Workers, supervisors, inspectors, risk assessors, and project designers engaged in lead-based paint activities.	562910	Provides standards that risk assessors would use to identify hazards and evaluate clearance tests; helps determine when certified professionals would need to be employed to perform lead cleanup
Training providers	Firms providing training services in lead-based paint activities	611519	Provides standards that training providers would have to teach in their courses
Federal agencies that own residential property		92511, 92811	Standards identify hazards that Federal agencies or purchasers of Federal property would have to abate in pre 1960 housing prior to sale, under Title X, section 1013.
Property owners that receive assistance through Federal housing programs	State and city public housing authorities, owners of multifamily rental properties that receive project-based assistance, owners of rental properties that lease units under HUD's tenant-based assistance program	53110, 531311	Standards identify hazards that property owners would have to abate or reduce as specified by regulations issued by HUD under authority of Title X, section 1012
Property owners	Owner occupants, rental property owners, public housing authorities, Federal agencies	531110, 531311	Standards identify hazards that, when known, would have to be disclosed under EPA/HUD joint regulations promulgated under Title X, section 1018

This listing is not intended to be exhaustive, but rather provides a guide for entities likely to be affected by this action. Other types of entities not listed in the table in this unit could also be affected. To determine whether you or your business is affected by this action, you should carefully examine the applicability provisions in relevant regulations. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, by

going directly to the Internet Home Page for this regulation at http://www.epa.gov/lead/leadhaz.htm and selecting the desired document. You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/ to obtain a copy of this final rule.

2. *In person.* The Agency has established an official record for this action under docket control number OPPTS–62156. The official record consists of the documents specifically referenced in this action, any public comments received during the comment period, and other information related to this action. This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official docket, which includes printed, paper versions of any electronic comments submitted during the comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Rm. B–607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260–7099.

II. Overview

A. Introduction

The Title X term ''lead-based paint hazard'' is intended to identify lead-based paint and all residential lead-containing dusts and soils regardless of the source of the lead, which, due to their condition and location, would result in adverse human health effects. One of the underlying principles of Title X is to move the focus of public and private sector decision makers away from the mere presence of lead-based paint, to the presence of lead-based paint hazards, for which more substantive action should be undertaken to control exposures, especially to young children. This regulation establishes hazard standards for residential lead-based paint, and residential dust and soil lead. The hazard standards for these three media, collectively, are statutorily defined as lead-based paint hazards.

B. Summary of Statutory Authority

The Residential Lead-Based Paint Hazard Reduction Act of 1992 was enacted as Title X of the Housing and Community Development Act of 1992. Title X establishes a comprehensive Federal program for reducing the risks from lead-based paint and certain lead hazards. The Title X program primarily gives authority to HUD and EPA, but affects a number of other Federal agencies. Among other things, Title X amended TSCA by adding TSCA Title IV, which specifically gives regulatory authority to EPA to cover, among other things, training of workers who deal with lead-based paint hazard abatement, the appropriate form of State and Tribal lead programs, and the identification of dangerous levels of lead. Title IV includes section 403. EPA is promulgating the standards for lead-based paint hazards under the authority of TSCA section 403, 15 U.S.C. 2683.

Section 403 requires EPA to promulgate regulations that ''identify . . . lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil'' for purposes of the entire Title X. Lead-based paint hazards, under TSCA section 401 (15 U.S.C. 2681), are defined as conditions of lead-based paint and lead-contaminated dust and soil that ''would result'' in adverse human health effects (15 U.S.C. 2681(10)). Lead-based paint is defined by statute as paint with lead levels equal to or exceeding 1.0 milligrams per square centimeter (mg/cm^2) or 0.5% by weight (see section 302(c) of the Lead-Poisoning Prevention Act (42 U.S.C. 4822(c)) and TSCA section 401(9) (15 U.S.C. 2681(9)). TSCA section 401 defines lead-contaminated dust as ''surface dust in residential dwellings'' that contains lead in excess of levels determined ''to pose a threat of adverse health effects'' (15 U.S. C. 2681(11)). TSCA section 401 defines lead-contaminated soil as ''bare soil on residential real property that contains lead at or in excess of levels determined to be hazardous to human health'' (15 U.S.C. 2681(12)).

EPA is also promulgating amendments to the regulations for lead-based paint activities under the authority of TSCA section 402 (15 U.S.C. 2682) and to the State and Tribal program authorization requirements under authority of TSCA section 404 (15 U.S.C. 2684). These changes are needed to ensure consistency among the various regulations covering lead risks under TSCA. Section 402 requires EPA to promulgate regulations establishing training and certification requirements for individuals and firms engaged in lead-based paint activities. Lead-based paint activities, in the case of target housing and child-occupied facilities, include risk assessment, inspection and abatement. See TSCA section 402(b)(1); 15 USC 2682(b)(1). To clarify this definition, EPA notes that lead-based paint activities do not include interim controls. These regulations ''shall contain standards for performing lead-based paint activities, taking into account reliability, effectiveness, and safety'' (15 U.S.C. 2682(a)(1)). Section 404 requires States and Tribes seeking to administer and enforce standards, regulations, or other requirements under section 402, 406, or both to seek authorization from EPA.

C. Guiding Principles

Reducing exposure to lead has been an important issue for EPA for more than 2 decades. Young children are especially vulnerable to the toxic effects of lead because their nervous systems are still developing and they absorb more of the lead to which they are exposed. Many of the health effects associated with lead are thought to be irreversible. Moreover, the effects at lower levels of exposure are often asymptomatic. In light of the impacts on children and the nature of the health effects, EPA's goal is to eliminate exposure to harmful levels of lead. This goal has informed Agency actions such as the decision to remove lead as an additive from gasoline as discussed in the preamble to the proposed rule (63 FR at 30305).

First and foremost, the Agency faces the difficulty of determining the level at which to set the standards given the uncertainties in information on cause and effect--what environmental levels in which specific medium may actually cause particular blood lead levels that are associated with adverse health effects. The Agency has tools, which are only generally consistent, that show that certain increases in environmental lead levels are associated with certain increases in blood lead levels. Given the range of uncertainty shown in its analysis supporting the establishment of a hazard level under this rule, EPA has developed a technical analysis that considers hazard standards for dust and soil at the lowest levels at which the analysis shows that across-the-board abatement on a national level could be justified. EPA recognizes, however that for any levels of lead in dust or soil judgment must be exercised as to how to treat the medium, and interim controls as well as abatement could be effective. In addition, EPA recommends that organizations and individuals consider some form of interim control in certain residential areas even where soil lead levels are below the hazard standard if there is a concern that children under 6 might spend substantial time in such areas, or there is potential for that soil to contribute to hazardous lead levels in play areas or dwellings. While the risks from lead at these lower levels are less than the hazard level, EPA believes that public health will be further protected if

owners and occupants of residential properties are encouraged to take actions to reduce the potential for lead exposure.

In performing its analyses for this rule, the Agency could not quantitatively compare interim control strategies with abatement strategies because there are only limited data available on the effectiveness of interim controls over extended periods of time, and those data which are available are not suitable for quantitative comparisons with abatements. In comparing interim control strategies with abatement strategies, one must make a number of assumptions concerning the costs of administrative management, and frequency of monitoring and renewal over the planning horizon. For the 50–year planning horizon which the Agency used in its dust and soil analyses, one would have to compare the time stream of interim control expenses, for as long as such expenses are necessary, and weigh the possible differences in potential blood-lead reductions, to make a fair comparison of abatement and interim control strategies.

Nevertheless, experience with interim control programs is increasing and certain organizations, particularly public health and housing agencies, believe they have been able to develop effective programs for interim controls which achieve virtually the same degree of risk reduction as do abatement programs, but at much reduced cost. EPA received comments on this issue during the public comment process. EPA wishes to encourage the continuing evaluation of such efforts because resources to deal with hazardous lead levels are often limited, and strategies which achieve comparable risk reduction, but at much reduced cost, have the potential to protect more children by allocating the limited resources more effectively. EPA believes that public and private organizations should evaluate both interim control and abatement strategies in determining the most effective course of action when dealing with dust and soil hazards.

In addition, EPA recommends that organizations and individuals consider some form of interim control response action in certain areas even where soil lead levels are below the hazard standard. This would apply if there is a concern that children under the age of 6 spend substantial time in such areas, or there is potential for that soil to contribute to hazardous lead levels in play areas or dwellings. While the risks from lead at these lower levels are less than at the hazard level, EPA believes that public health will be further protected if owners and occupants of residential properties are aware of such contamination and are encouraged to take actions to reduce the potential for lead exposures.

For determining a paint lead hazard EPA faced a data problem different from that faced with respect to dust and soil hazards. For dust and soil, EPA had substantial raw data on environmental levels and blood lead levels, even though it faced substantial uncertainty in correlating the levels. For lead-based paint, as discussed later in this preamble, the Agency had no data by which it could select a threshold below which the paint would not be a hazard. EPA, therefore, could not apply the same analysis for the paint hazard determination as it did for the dust and soil hazard determinations. Comments indicated that even very tiny amounts of deteriorated lead-based paint are sufficient in certain circumstances to result in adverse health effects. Accordingly, EPA has generally designated any amount of deteriorated paint as a lead-based paint lead hazard. Nevertheless, as with dust and soil hazards, EPA would not recommend full scale abatement be undertaken for all paint lead hazards. Instead, the Agency wishes the public to be aware that any deteriorated lead-based paint presents enough of a risk that it should be stabilized and carefully monitored if it is not abated.

Controlling exposure to lead in the residential environment presents EPA with challenges that, in important respects, are different from and often more complex than those the Agency deals with in other regulatory contexts. Among the challenges of this regulation is that it requires the Agency to address exposure from the past use of products that contained lead rather than current products and/or processes that introduce lead into the environment. Assuming that there are safe and available substitutes, the government can eliminate lead from an existing product if the risk warrants such removal (e.g., gasoline, solder for water pipes and food cans). Removing lead that is already in the environment is far more difficult. It would have been better that lead never found its way into paint that exists today in approximately 64 million homes. However, since it is so pervasive, EPA is faced with a number of dilemmas. First, the number of properties that have some form of lead is enormous. However, the number of buildings with lead paint an dust that present a hazard is, relatively, much lower. The Agency must therefore distinguish which of these lead conditions need to be controlled. Because there is a great deal of variability among properties containing lead paint, our ability to identify which properties present risks is limited. Moreover, the exposure risk to individuals, even if there were not such a large number of affected properties, can be compounded by child-specific factors (e.g., hand-to-mouth behavior, pica, nutrition, hygiene).

In addition, the success of the program will largely rely upon the voluntary participation of States and Tribes, as well as counties and cities, to implement the program and upon property owners to follow the standards and EPA's recommendations. If EPA were to set unreasonable standards (e.g., standards that would recommend removal of all lead from paint, dust, and soil), States and Tribes may choose to opt out of the Title X lead program and property owners may choose to ignore EPA's advice, believing it lacks credibility and practical value. Consequently, EPA needed to develop standards that would protect children without wasting resources by chasing risks of negligible importance and that would be accepted as reasonable by States, Tribes, local governments, and property owners.

Three other considerations also merit the public's attention. First, as noted, the standards are designed to focus resources on the worst problems. If property owners are able to address less pressing problems (e.g., deteriorated paint below the minimum area threshold), EPA encourages them to take action. EPA also encourages States, Tribes, and local governments to adopt more stringent standards if local circumstances warrant such action.

Second, the standards alone cannot solve the lead problem. They are part of a broader program designed to educate the public and raise public awareness, empower and protect consumers, and provide helpful technical information that professionals can use to identify and control lead hazards. EPA has developed and implemented an active public education and outreach program consisting of a toll-free hotline (1–800–424–LEAD) co-sponsored with HUD and U.S. Centers for Disease Control and Prevention (CDCP), public service announcements, poster campaigns, distribution of a parent's guide through grocery stores, slides in movie theaters, and an outreach campaign with the National Parent Teachers Association, the National Association of Child Care Providers, and public libraries.

Consumer empowerment and protection efforts include the hazard disclosure regulations jointly issued with HUD training and certification

standards for individuals and firms engaged in lead-based paint activities, and the pre-renovation education rule that requires renovation and remodeling contractors to provide the EPA pamphlet ''Protect Your Family from Lead in Your Home'' to occupants prior to the start of renovation and remodeling projects. In addition, under section 402 of TSCA, EPA is currently developing training and certification requirements for renovation and remodeling contractors whose activities may create lead hazards.

EPA and other Federal agencies continue to conduct field studies to identify and evaluate lower cost products and technologies for evaluating and controlling lead-based paint hazards. The findings of these studies are distributed to professionals through our lead hotline, EPA's website (www.epa.gov/lead) and at other agencies' websites, and through on-going contact with trade and professional associations. The standards, combined with these other efforts, provide a comprehensive program designed to reduce and eventually help eliminate lead in residential paint, dust, and soil as a cause of childhood lead poisoning.

Third, these standards are based on the best science available to the Agency. EPA recognizes, however, that the science is constantly developing and with it our understanding of the relationship between lead in the environment and human exposure and the relationship between exposure and health impacts. If new data become available (e.g., empirical data showing that very small amounts of deteriorated paint pose a serious health risk or data showing that hazard control activities are more effective at reducing long-term dust-lead levels than assumed by EPA), the Agency will consider changing the standards to reflect these data. If the data indicate that the standards should be changed and they meet EPA's quality criteria, the Agency will consider publishing the data for public review and comment and amending today's regulation.

D. Regulatory Approach

1. *Uniform national standards.* EPA is issuing uniform national standards in this rule. The rationale for adopting uniform national standards is found on pages 63 FR 30307 to 30308 of the preamble to the proposed rule. EPA summarizes this reasoning in the following paragraphs.

EPA stated that the relationship between environmental lead levels (from paint, dust, and soil) and their effects on the health of exposed children, which forms the basis for this rule, is complex, and is dependent upon numerous site-specific and child-specific factors. Where more site-specific factors can be considered on a smaller (residence or community) scale, estimates of the effects of environmental levels on blood lead can be more accurate. The data needed, however, are not available for communities nationwide. In contrast, national data on lead in paint, dust, and soil are currently available. Even if data were available, the residence or community scale standards would still not account for variability in exposure influenced by child-specific factors (e.g., hand-to-mouth behavior, hygiene, and nutrition). Detailed evaluations that considered the specifics of individual communities would generally require information for each residence to evaluate the impact of environmental lead on children.

In addition, uniform national standards provide a fixed basis of comparison for all homes. National standards can be used to compare properties and establish priorities. This would be extremely difficult to accomplish if there were the numerous standards specific to individual communities.

EPA also took into account that certain segments of the population have a higher incidence of elevated blood-lead levels (e.g., minority and low-income children). Because estimates of the relationship between environmental lead levels and children's health effects are not sufficiently refined to distinguish relationships for particular subsets of the general population of children, EPA is choosing to emphasize program implementation (e.g., training, education, and environmental justice grants), which the Agency considers a more effective and simpler approach to address vulnerable communities rather than setting community-specific standards. EPA preferred to establish a simple, set of standards that could easily be adopted by States, allowing them to tailor the standards, should they so choose. This allows States greater flexibility to establish and implement their programs while a national, baseline level of protection to children is maintained.

2. *Media-specific standards.* A second basic issue that shaped EPA's standard-setting approach involves the fact that a child's total lead exposure is the sum of contributions from numerous sources, including paint, dust, soil, and others. Specifically, EPA had to decide whether to set separate, independent standards for paint, dust, and soil or to integrate the standards.

Under the first option, EPA would establish a fixed standard for each medium without considering the varying conditions in the other media. For example, the soil standard would remain constant, regardless of whether dust lead levels were high or low. The chief advantage of this option is that the standards are simple to understand and use.

A potential disadvantage of this approach is that a standard could be established for a particular medium that does not consider the total exposure of a child (i.e., exposures from all other media). To address this potential shortcoming, the Agency considered candidate sets of standards for dust, lead, and paint together so that its comparisons of candidate standards reflected exposures to all media. Consequently, the standards, although they are medium-specific numbers will effectively identify hazards as long as all media are evaluated and compared to the standards.

Under the second option, EPA would set standards to account for total lead exposure from all media. Under a joint standard, the standard for each medium would vary, depending on the conditions in the other media. For a graphical [illustration of this option, see page 30308 of the preamble to the proposed rule. The major advantage of the joint standards is that they avoid anomalous situations. For example, it stands to reason that if both dust and soil measurements are just below the hazard levels--35 $\mu g/ft^2$ on the floor and 1,175 parts per million (ppm) in the non-play area--the situation is more dangerous than if one measurement is above the hazard level--e.g. 1,225 ppm for soil--and floor dust is at zero. Yet the first set of measurements would not constitute a hazard and the second set would. In these circumstances, joint standards may better reflect the total exposure and risk. Furthermore, for this option to be truly effective, EPA would need to know the levels from all sources of lead exposure and how they relate to blood lead levels individually and in various combinations. EPA, currently, lacks the analytical tools to support selection of joint standards. In addition, EPA is endeavoring to set the media specific hazard standards low enough that hazardous situations will not occur if both soil and dust are just below the standards. In such a case, the media specific standards could be overinclusive. The Agency, however, believes that this approach is appropriate to protect public health. Accordingly, in this rule EPA is establishing media-specific standards. Additional explanation for this decision

can be found on pages 30308 and 30309 of the preamble to the proposed rule.

E. Applicability and Uses of the Standards

The standards established in this rule apply to target housing (i.e., most pre-1978 housing) and child-occupied facilities (pre-1978 non-residential properties where children under the age of 6 spend a significant amount of time such as daycare centers and kindergartens). The standards are intended to be used prospectively. That is, they should be used to identify properties that present risks to children before children are harmed. This, of course, would not prevent them from being used retrospectively in the case of environmental intervention blood lead investigations and clearance of resulting lead hazard control activities.

These standards are not appropriate as the sole source of information to use when identifying the source of exposure for a lead-poisoned child. When a property is being evaluated in response to an identification of a lead-poisoned child, the risk assessor in cooperation with local public health officials should identify and consider all sources of lead exposure. For example, a risk assessor should consider lead in drinking water as well as the presence of any amount of deteriorated lead-based paint.

Within the scope of Title X, these regulatory standards will help support and implement major provisions of the statute. They will be incorporated into the risk assessment work practice standards, providing the basis for risk assessors to determine whether lead-based paint hazards are present. By helping to determine when a hazard is present, the standards will help determine when a hazard control activity must be performed by certified personnel. EPA further notes that only abatement of lead-based paint hazards specifically hazardous lead-based paint, dust-lead hazards or soil-lead hazards identified in 40 CFR 745.65 requires certified personnel. This is because ''abatement'' is defined in 40 CFR 745.223 as ''measures designed to permanently eliminate lead-based paint hazards.'' Thus, permanent elimination of lead-based paint, and dust or soil lead would not require the use of certified personnel unless lead-based paint hazards are present in those media.

States and Tribes wishing to obtain or retain authorization to administer and enforce training and certification programs must incorporate hazard standards as protective as the standards in this rule. Provisions for State and Tribal authorization are described at 40 CFR part 745, subpart Q. These standards will also help property owners comply with section 1018 by establishing what conditions must be disclosed to prospective purchasers and renters as *lead-based paint hazards* prior to the sale or rental of target housing. HUD, the Department of Defense (DoD), and other Federal agencies will use these standards in implementing or overseeing the evaluation and control of hazards in Federally-assisted housing and Federally-owned housing prior to disposition. (24 CFR part 35)

Under section 1018 of Title X (42 U.S.C. 4852d), EPA and HUD have jointly developed regulations requiring a seller or lessor of most pre-1978 housing to disclose the presence of any known lead-based paint and lead-based paint hazards to the purchaser or lessee (24 CFR part 35, subpart A; 40 CFR part 745, subpart F). When these section 403 rules become effective, lead-based paint hazards in lead paint, dust or soil will need to be disclosed. EPA further notes, however, that under the section 1018 rules, the seller or lessor also must provide the purchaser or lessee any available records or reports ''pertaining to'' lead-based paint, lead-based paint hazards and/or any lead hazard evaluative reports available to the sellor or lessor (section 1018(a)(1)(B). See 40 CFR 745.107(a)(4). Accordingly, if a seller or lessor has a report showing lead is present in levels that would not constitute a hazard, that report must also be disclosed. Thus, disclosure is required under section 1018 even if dust and soil levels are less than the hazards. EPA notes, however, that with respect only to leases of target housing, disclosure is not required in the limited circumstance where the housing has been found to be lead-based paint free by a certified inspector (24 CFR 35.82; 40 CFR 745.101), although voluntary disclosure of such certifications is encouraged.

Beyond the scope of Title X, these standards will guide the control of lead-based paint hazards in the nation's housing stock.

Although other regulations (e.g., hazard evaluation and control in housing receiving Federal assistance and Federally-owned housing prior to sale) may require property owners to evaluate properties for the presence and/or control of lead hazards, today's action does not contain such requirements. Specific requirements are determined by the particular State, Federal, and local government regulations which mandate actions when health hazards are found in target housing or child-occupied facilities. EPA, however, strongly recommends that property owners or other decision makers take appropriate actions to reduce or eliminate hazards. Finally, the standards provide property owners and other decision makers with the Federal government's best judgement concerning lead dangers in residential paint, dust, and soil.

The standards were established assuming that property owners and other decision makers would identify and control hazards in all three media (i.e., paint, dust, and soil). Failure to take a multimedia approach may not provide adequate protection to children. First, the protectiveness of the standards assumes that all media will be appropriately addressed. Second, failure to address one or more medium leaves children at risk from exposure to lead in media that are not addressed. Third, failure to address one or more media reduces the effectiveness of hazard control actions that are taken due to recontamination of one media from lead in another. Fourth, the Agency believes that soil can be a source of exposure whenever it is accessible for either incidental ingestion or tracking into a home, and that while grass and other coverings may be effective in significantly reducing potential exposures, such coverings must be maintained in order to provide continuing protection.

F. Summary of the Final Rule

1. *Hazardous lead-based paint (§ 745.65(a)).* The hazard standard for lead-based paint, called the ''paint lead hazard,'' is any of the following:

a. Any lead-based paint on a friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface underneath the friction surface are equal to or greater than the dust hazard levels.

b. Any damaged or otherwise deteriorated lead-based paint on an impact surface that is caused by impact from a related building component.

c. Any chewable lead-based paint surface on which there is evidence of teeth marks.

d. Any other deteriorated lead-based paint in residential buildings or child-occupied facility or on the exterior of any residential building or child-occupied facility.

The purpose of identifying almost all deteriorated lead-based paint as a paint lead hazard is to alert the public to the fact that all deteriorated lead-based paint should be addressed--through use of paint stabilization or interim controls. Something less than abatement and certified personnel, however, would be needed to undertake interim controls or to abate lower levels of deterioration.

Two existing HUD and EPA rules provide the applicable standards: HUD rules under sections 1012 and 1013 of Title X published on September 15, 1999 (61 FR 50140), and EPA work practice rules under section 402 of TSCA published on August 29, 1996 (61 FR 45778) (FRL–5389–9). In general, these rules provide that occupant protection procedures, clearance testing, use of certified personnel or other similar specialized lead hazard control practices and procedures are not required if one or more of the following conditions exist:

a. Two square feet or less of deteriorated lead-based paint in a room.

b. Twenty square feet or less of deteriorated exterior lead-based paint;

c. Ten percent of the total surface area on an interior or exterior type of component with a small surface area consist of deteriorated lead-based paint.

2. *Dust standards*. Today's regulation includes two standardsfor dust: hazard levels for floors (including carpeted floors) and interior window sills (§ 745.65(b)) and clearance standards for floors (including carpeted floors), interior window sills, and window troughs (§ 745.227(e)(8)(viii)). The dust-lead hazard standards are 40 μg/ft^2 for floors based on a weighted average of all wipe samples and 250 μg/ft^2 for interior window sills based on a weighted average of all wipe samples. The weighted average, or weighted arithmetic mean, means the arithmetic mean of sample results weighted by the number of subsamples in each sample. Its purpose is to give influence to a sample relative to the surface area it represents.

The clearance standards for dust following an abatement are 40 μg/ft^2 for floors, 250 μg/ft^2 for interior window sills, and 400 μg/ft^2 for window troughs. The dust-lead level must be less than the applicable standard for the surface to pass clearance. Clearance standards are used to evaluate the effectiveness of cleaning following an abatement, and EPA may also use these standards in future rulemakings to evaluate the effectiveness of cleaning following a renovation and remodeling project. Properties that undergo abatement must pass clearance according to the work practice standards for abatement found at 40 CFR 745.227. If a property fails clearance, it must be recleaned until it passes, although it is not automatically necessary to reclean the entire property when clearance fails, such as when some of the visual and dust-testing clearance results have indicated that portions of the property are already cleared.

3. *Soil standards*. Today's regulation establishes the following standards for bare residential soil: a hazard standard of 400 ppm by weight in play areas based on the play area bare soil sample and an average of 1,200 ppm in bare soil in the remainder of the yard.based on an average of all other samples collected. See § 745.65(c). The final rule also identifies lead-contaminated soil as soil with levels equal to or greater than these soil-lead hazard standards.

Property owners and other decision makers should implement effective measures to reduce or prevent childrens' exposure to lead in soil that exceeds these levels. These measures may incorporate, but are not limited to, interim controls that include covering bare soil and placement of washable doormats in entryways. The need for more permanent controls should be determined with consideration of local conditions and usage patterns, the relative risks from different lead sources, and the potential for exposures to change over time.

4. *Summary of other actions*. Today's rule also amends existing regulations for lead-based paint activities including:

a. Requirements for interpreting the results of a lead-based paint risk assessment sampling for purposes of determining if lead-based paint hazards are present.

b. Changes to the risk assessment work practice standards at 40 CFR 745.227 to require testing of all deteriorated paint on surfaces with a distinct painting history to determine if the paint is lead-based.

c. Changes to the dust and soil sampling locations in the risk assessment work practice standards at 40 CFR 745.227.

d. Work practice standards for the management of soil removed during an abatement.

e. Amendments to the State and Tribal program authorization requirements under 40 CFR part 745, subpart Q; and

f. Amendment to the definition of ''abatement'' at 40 CFR 745.223 to make it clear that abatement does not include removal of paint, dust, and soil unless lead-based paint hazards are present in those media.

G. Limitations of the Hazard Standards

As stated in the proposed rule (63 FR at 30304), there is significant confusion about the requirements and purpose of the TSCA section 403 regulations. Consequently, EPA felt it necessary in the preamble to the proposed rule to highlight major limitations and other issues related to the scope and use of the regulation. These statements continue to apply. To summarize, the regulation does not establish a new definition for lead-based paint. The hazard standards apply to conditions observed when the risk assessment was performed. The standards do not address the potential for a hazard to develop. The standards apply to target housing, but may be used as guidance for other residential property. Finally, the standards are intended to identify dangerous levels of lead, not housing that is free from risks associated with exposure to lead.

As stated in Unit II.F.3., today's rule establishes two hazard standards for bare residential soil; 400 ppm for play areas and an average of 1,200 ppm for the rest of the yard. EPA recommends that organizations and individuals consider some action in certain areas even where levels in bare soils are below the hazard standard, particularly, if there is a concern that children 6 years and under might spend substantial time in such areas, or if there is concern that the bare soil in such areas may contribute to lead levels in the dwelling, or in the play areas. However, this rule does not mandate that any action be implemented when levels are found to be below the lead hazard standard. Moreover, the kind of response that organizations and individuals might consider could include modest actions such as planting grass (or other ground cover) to more extensive actions such as covering the bare soil with several inches of clean fill.

As indicated in Unit II.E., it is also important to emphasize that this rule only applies to pre-1978 target housing and certain child-occupied facilities, and that these standards were not intended to identify potential hazards in other settings. If one chooses to apply the hazard level to situations beyond the scope of Title X, care must be taken to ensure that the action taken in such settings is appropriate to the circumstances presented in that situation, and that the action is adequate to provide any necessary protection for children exposed. See also Unit IV.D. for a discussion regarding the relationship of the soil hazard standard to Superfund soil cleanup standards.

H. Preamble Overview

The remainder of this preamble consists of four units. Unit III. presents an explanation of the Agency's decisions. It includes a summary of the proposal, identifies the major changes between the proposed and final rules, and explains the changes. Unit IV. presents a discussion of some of the more significant issues raised by the public comments. Unit V. contains the

references for sources used in this preamble. Unit VI. is the regulatory assessment unit, which deals with the Federal requirements for agency rulemaking that are imposed by various statutes and executive orders. Unit VII. discusses the Congressional Review Act requirements.

III. Explanation of the Agency's Decisions

A. Summary of the Proposed Regulation

EPA published the proposed regulations on June 3, 1998 (63 FR 30302) (FRL–5791–9). The proposed standard for hazardous lead-based paint was lead-based paint in poor condition, defined as more than 10 ft^2 of deteriorated lead-based paint on exterior components with large surface areas, more than 2 ft^2 of deteriorated lead-based paint on interior components with large surface areas, or deteriorated lead based paint on more than 10% of the total surface area of interior or exterior components with small surface areas. Lesser amounts of deteriorated paint were considered *de minimis* levels and were not considered hazards. The proposed standard for a dust lead hazard was the average level of lead in dust that equals or exceeds 50 $\mu g/ft^2$ on uncarpeted floors and 250 $\mu g/ft^2$ on interior windows sills. The proposed standard for soil-lead hazard was lead that equals or exceeds 2,000 ppm based on a yard-wide average soil-lead concentration. A soil-lead level of concern, proposed to be 400 ppm, was included in draft guidance but not in the proposed regulation. The statutory basis for the level of concern was the section 403 requirement that EPA identify ''lead-contaminated soil,'' which the Agency interpreted to be a level less than the soil-lead hazard. EPA used the term ''level of concern'' instead of ''lead-contaminated soil. EPA proposed that lead-based paint hazards be identified by certified risk assessors performing risk assessments according to the work practice standards at 40 CFR 745.227.

The June 3, 1998 document also proposed amendments to existing regulations for lead-based paint activities including:

1. Clearance standards for dust following an abatement of 50 $\mu g/ft^2$ for uncarpeted floors, 250 $\mu g/ft^2$ for interior window sills, and 800 $\mu g/ft^2$ for window troughs.

2. Requirements for interpreting the results of a lead-based paint risk assessment sampling for purposes of determining if lead-based paint hazards are present.

3. Changes to the dust and soil sampling locations in the risk assessment work practice standards at 40 CFR 745.227.

4. Work practice standards for the management of soil removed during an abatement; and

5. Amendments to the State and Tribal program authorization requirements under 40 CFR part 745, subpart Q.

B. Summary of Significant Changes from the Proposed Regulation and Other Major Decisions

This section of the preamble briefly presents the major changes between the proposal and final rule. EPA also identifies major provisions of the proposed regulation that remain unchanged in the final rule. Unit II.D. of the preamble presents the Agency's explanation for these decisions.

1. *Dust standards*. The final rule changes the lead-based paint hazard standard for dust, known as the dust-lead hazard, and the standard for dust clearance for floors to 40 $\mu g/ft^2$. In addition, the dust-lead hazard will apply to all floors, including carpeted floors. It will not be limited to bare floors. The final rule does not change the dust-lead hazard for interior window sills. Today's action lowers the clearance level for window troughs from the proposed 800 $\mu g/ft^2$ to 400 $\mu g/ft^2$. In addition, the final rule modifies the method for interpreting composite dust clearance samples. Under the proposed rule, the result of the composite sample would have been compared to the clearance level divided by the number of subsamples in the composite. The final rule requires the result of the composite sample to be compared to the clearance level divided by half the number of subsamples in the composite.

2. *Soil standards*. With respect to the soil standards, there are several changes from the proposed rule. First, EPA is not establishing any distinction between lead-contaminated soil (soil lead ''level of concern'') and soil-lead hazards. Instead, EPA is, in the preamble, simply identifying lead-contaminated soil as soil with levels equal to or greater than the soil-lead hazard standards. For purposes of this rule ''lead-contaminated soil'' is the same as a ''lead-based paint hazard'' based on soil lead.''

Second, in the final rule EPA is establishing the lead-based paint hazard standard for bare soil, known as the soil-lead hazard standard, to have one hazard level for play areas and another for the remainder of the yard. The proposed rule did not give special attention to play areas and made the hazard determination based on the whole yard only. From the proposed 2,000 ppm for bare soil in the entire yard, EPA is setting a final soil-lead hazard of 400 ppm for bare soil in play areas and an average of 1,200 ppm for bare soil in the non-play area portion of the yard.

3. *Paint standards*. The paint component of the lead-based paint hazard standards is known as the paint-lead hazard. The paint-lead hazard consists of three standards: Deteriorated lead-based paint; lead-based paint on friction and impact surfaces; and lead-based paint on accessible (chewable) surfaces.

a. *Deteriorated paint*. EPA considers that, in general, any deteriorated lead-based paint needs to be addressed and should be considered a paint-lead hazard. Accordingly, in the final rule the Agency does not have a *de minimis* level of deteriorated paint for the paint-lead hazard. Instead, the final rule simply refers to work practice and certification regulations issued by HUD and EPA that apply to dealing with paint-lead hazards. These regulations provide that occupant protection procedures, clearance testing, use of certified personnel or other similar specialized lead hazard control practices and procedures are not required at lesser levels of paint deterioration. These specific levels of deterioration are (i) Two square feet or less of deteriorated lead-based paint per room; (ii) twenty square feet or less of deteriorated exterior lead-based paint; (iii) ten percent of the total surface area on an interior or exterior type of component with a small surface area.

b. *Friction and impact surfaces*. The standard in the final rule for the paint-lead hazard on friction surfaces is lead-based paint that is subject to abrasion where the lead dust levels on the nearest horizontal surface underneath the friction surface are equal to or greater than the lead-dust hazard levels. The paint-lead hazard for impact surfaces is any damaged or otherwise deteriorated paint on an impact surface that is cause by impact from a related building component. No minimum area threshold of paint deterioration applies to friction or impact surfaces. In the proposed rule, EPA did not include a preferred option for these surfaces. The Agency, instead, solicited public comment on a range of options including: Lead-based paint regardless of condition on a friction/impact surface; abraded lead-based paint on a friction/impact surface; and no separate standard.

c. *Surfaces accessible for chewing or mouthing*. The standard for the paint-

lead hazard on accessible surfaces, referred to as ''chewable'' surfaces in the final rule, is any chewable lead-based paint surface on which there is evidence of teeth marks. No minimum area threshold applies to deteriorated lead-based paint on accessible surfaces. In the proposed rule, EPA did not include a preferred option for these surfaces. The Agency, instead, solicited public comment on a range of options including: Lead-based paint regardless of condition on interior window sills up to 5 feet off the floor; and no separate standard for accessible surfaces. EPA has eliminated the 5–foot requirement.

4. *Requiring certified risk assessors to determine the existence of lead-based paint hazards.* The final rule does not include a requirement that the presence of lead-based paint hazards must be determined by certified risk assessors following the risk assessment work practice standards at 40 CFR 745.227.

C. Explanation of the Agency's Decisions

In this section of the preamble, EPA provides its reasons for choosing the final TSCA section 403 standards for lead-based paint hazards (which includes paint-lead, dust-lead, and soil-lead hazards) and its final determination for what constitutes lead-contaminated dust and residential soil. In addition, EPA provides its reasons for establishing the clearance levels for household dust--measures of dust in lead that will show that hazards have been appropriately cleaned.

The choice of the particular methodologies used to develop each of these standards constitutes another important set of decisions. Hazard levels for dust and soil were developed using an analysis of risk, the potential for risk reduction (considering uncertainties in the data and scientific evidence describing the risks), and the cost of reducing risk. In determining the paint-lead hazard, EPA has decided that any deteriorated lead-based paint would result in adverse health effects, based on information submitted in public comments and other information in the rulemaking record. The Agency has been unable to determine any level of deteriorated lead-based paint that should not be considered a paint-lead hazard.

The general outline of these methodologies is referred to in later sections of this Unit and, where applicable, incorporates into the final rule those decisions made in the preamble to the proposed rule.

1. *Basis for dust and soil standards.* As a preliminary matter, EPA has found, after considering all significant public comments and all other information in the rulemaking record, that the legal interpretations and policy decisions in the preamble to the proposed rule form the basis for the final decisions discussed in this preamble, except as indicated below. EPA hereby incorporates, for purposes of this final rule, the relevant reasoning and analyses from the proposed preamble, as indicated below. Any modifications to the analyses or reasoning from the preamble to the proposed rule will be specifically explained in this preamble, the Reponse to Comment (RTC) document, or other documents in the record, and are supported by the record for the final rule.

a. *Legal basis.* Details of the basic legal structure of Title X and the legal effect of the issuance of regulations under TSCA section 403, including the responsibilities of EPA and HUD, are set forth in the preamble to the proposed rule (63 FR 30306) and need not be repeated here. There EPA provided a detailed discussion of its views at the time of the statutory mandate and the statutory criteria, including the Agency's interpretation of relevant terms and the statutory basis for the Agency's decision to use particular criteria to develop the determination for what constitutes lead-contaminated dust and lead-contaminated soil and the hazard standards for dust, soil and paint at (63 FR at 30311–30315). EPA has modified some of these interpretations and retains others, as discussed below.

EPA needs to define three terms under TSCA section 403, ''lead-based paint hazards,'' ''lead-contaminated dust'' and ''lead-contaminated soil.'' Lead-based paint hazards consist of lead-contaminated paint, lead-contaminated dust and lead-contaminated soil that ''would result'' in adverse health effects.

Section 401(9) of TSCA provides a definition of lead-based paint, which EPA interprets to be lead-contaminated paint for purposes of this rule. EPA noted that lead-based paint is not, under the statute, a risk-based term, but only a benchmark that identifies material subject to jurisdiction of the authorities of TSCA and Title X. Not all lead-based paint is a hazard, only that paint which EPA determines ''would result'' in adverse health effects. EPA has determined, as discussed below, that the dust and soil levels designated as lead-based paint hazards are also identified as ''lead-contaminated dust'' and ''lead-contaminated soil.'' This equating of dust and soil contamination with ''lead-based paint hazards'' caused by dust and soil lead represents a change from the reasoning in the preamble to the proposed rule. EPA's reasons for this change are discussed below.

EPA generally refers to the hazards in each of the media as ''paint-lead hazards,'' ''dust-lead hazards'' and ''soil-lead hazards.''

i. *Decision on contaminated dust and soil.* While section 403 obligates the Agency to identify lead-based paint hazards, lead contaminated dust, and lead-contaminated soil, the legislative history and statutory text are themselves silent on how Congress intended the Agency to differentiate between the standard for soil contamination (the level of lead in soil determined to be hazardous to human health), dust contamination (the level of lead in dust that poses a threat of adverse health effects in pregnant women or young children), and the levels of contaminated dust or soil that constitute a lead-based paint hazard (a condition that would result in adverse human health effects). Further, the terms ''lead-contaminated dust'' and ''lead-contaminated soil'' have no significance under either TSCA or Title X except insofar as the level of contaminated dust or soil constitutes a ''lead-based paint hazard''.

In the proposed rule EPA considered that, because the statute required the identification of ''lead contaminated'' dust and soil, the Agency needed to establish separate levels for these terms than for ''lead-based paint hazards'' resulting from contaminated dust or soil. Furthermore, EPA proposed, based on the statutory language and the structure of the statute, that the determination of whether dust or soil were contaminated required less certainty than whether such dust or soil constituted a hazard. See 63 FR 30311-12. In the preamble to the proposed rule EPA set the ''contamination'' levels, then called ''levels of concern,'' at those levels the Agency determined could result in a 1 to 5% probability of an individual child's exceeding a blood lead level of 10 µg/dL. See 63 FR 30316-30317.

EPA noted, however, that the terms, ''lead-contaminated'' dust and soil have no direct effect on any activities subject to regulation under Title X. For example, no certification requirements are imposed for persons who remove lead-contaminated soil, only for those who remove soil associated with soil-lead hazards. Because the contamination levels do not affect other activities under Title X or TSCA Title IV, EPA proposed not to include them in the regulatory language. EPA only proposed to adopt in guidance to accompany the final rule a separate level for lead-contaminated soil of 400

ppm for the entire yard. EPA did not propose to adopt a separate standard for contaminated dust, since it found substantial overlap in its analysis and could not distinguish between dust-lead contamination and dust-lead hazards.

EPA received a significant number of comments criticizing the establishment of these ''contamination'' levels, particularly for soil, primarily because setting two levels for ''contamination'' and ''hazard'' would confuse the public. Other comments claimed EPA had no authority to establish separate contamination levels, as opposed to hazard levels.

While the Agency clearly has authority to establish separate levels for contaminated dust and soil, given the comments, the lack of clear statutory direction, and the lack of significance of the terms in the statutory structure, the Agency has determined not to establish any separate levels for contaminated dust or soil beyond those levels that constitute a lead-based paint hazard. The Agency believes it sufficient for purposes of TSCA and Title X to conclude that, at a minimum, the quantity of lead in dust or soil found to result in conditions that cause exposure to lead that would result in adverse human health effects (i.e., constitutes a lead-based paint hazard) is ''lead-contaminated dust'' and ''lead-contaminated soil,'' respectively. Accordingly, for purposes of this regulation, the dust and soil levels designated as lead-based paint hazards are also identified as ''lead-contaminated dust'' and ''lead-contaminated soil''.

ii. *Weight of evidence for dust and soil hazard standards.* EPA's dilemma in determining what constitutes dust-lead and soil-lead hazards is based on the Agency's recognition that any determination of hazard requires a great deal of judgment in the case of lead health risks where, ''as a practical matter, all the scientific evidence is uncertain to some degree . . .'' (See preamble to the proposed rule at 63 FR 30313.) Making judgments on the science varies to a large extent with respect to three issues: How to determine which blood lead levels are truly hazardous; how to interpret the statutory language ''result in adverse human health effects,'' when uncertainties exist; and how best to account for uncertainties in the risk analyses that relate environmental lead levels to blood lead levels and the prevalence data that is used in this analysis.

The resolution of these issues, at best, produces a continuum where, at one end, blood and environmental levels exist that everyone would agree constitute a hazard. At the other end, approaching blood lead levels in the general population (averaging lower than 5 μg/dL) or typical environmental levels (generally, less than the hazard levels found in this regulation), greater uncertainty exists on how to model the likelihood of health effects. This is compounded by having to factor in uncertainties of the effects of both blood lead levels and the associated environmental levels. This is because, even if EPA has confidence in the blood lead levels of concern, the Agency still faces the uncertainty of associating blood lead with environmental levels in each medium, as well as possible effects from other sources--for example, water and air emissions.

In addressing the first issue, the Agency has chosen 10 μg/dL as the blood-lead level of concern. This value is equal to the level of concern recommended by the CDCP and the Agency's reasons for choosing this value are explained in the next section of this preamble.

As to the second issue, the challenge to the Agency is how to deal with the statutory criterion, ''would result in adverse human health effects.'' This is especially problematic because the statutory mandated activity that requires EPA to choose a cutoff for when this risk exists does not lend itself to a straightforward empirical analysis that provides bright lines for decision makers. Even if the science and environmental-lead prevalence data were perfect, there would likely be no agreement on the level, or certainty, of risk that is envisioned in the phrase ''would result in adverse human health effects.'' Thus, it would not be appropriate to base a lead-based paint hazard standard on any specific probability of exceeding any specific blood-lead level.

The Agency therefore elected to take a pragmatic approach to setting the hazard standards namely, evaluating the amount of risk reduction that the hazard standards could provide. That is, rather than trying to select standards based solely on model-based probability distributions (which is even further complicated by the fact that different models produce different results), the Agency looked at the consequences of the standards based on the assumption that, if EPA calls something a ''lead-based paint hazard,'' all persons would act rationally in their own best interests and would permanently eliminate (abate) these hazards before a child is about to become exposed to them. This is the so-called ''normative'' analysis referred to in the preambles to the proposed and final rule and discussed in detail in the economic analyses and preambles for the proposed and final rules. (EPA's analysis for using this method for determining what constitutes dust and soil hazards is discussed in detail in the preamble to the proposed rule at 30312-15. That analysis is incorporated as the final interpretation of the Agency on this matter and will not be repeated in great detail here. Later in this preamble, EPA responds to the various public comments on its analysis of the appropriate method for determining dust and soil lead-hazards under TSCA section 403.)

Also, identification of lead-based paint hazards under this regulation is sure to have impacts that could be expensive even though the range of expenses is, itself, difficult to resolve because of the uncertainty of individual behavior and the willingness of individuals to accept risks that EPA may identify. Thus, if EPA were to choose standards that are too low, the public could be unable to distinguish between trivial risks at the low levels of lead from the more serious risks at higher levels. This could result in clean up for little to no health benefit, or conversely, it could result in almost no clean up because persons would question the credibility of the ''hazard'' determination. Thus, they may ignore even those high risk situations that need to be controlled. On the other hand, if the Agency chooses standards that are too high, actual adverse effects could occur at levels below that. EPA's dilemma is to draw this line.

Based on the language of section 403, the purposes of Title X and its legislative history, and basic policy decisions, EPA determined that it was a reasonable exercise of its discretion to draw this line based on consideration of the potential for risk reduction of any action taken (considering uncertainties in the data and the scientific evidence describing the risks) and whether such risk reductions are commensurate with the costs of those actions. This is commonly referred to as cost-benefit balancing. In this rule, EPA used cost-benefit balancing to assist in identifying the hazard standards. This method was useful because available data run through various models showed a range of environmental levels that could be associated with a particular blood-lead level (the surrogate used to approximate risk) and the potential reduction in blood-lead concentration/risk that could result from eliminating or controlling the environmental level. Given this range, EPA used cost-benefit balancing to assist in selecting the specific

standards for this rule from within the range bounded by the results of the models.

Using this approach, the Agency is better able to deal with the third issue identified above how to best consider and account for the strengths and weaknesses of its risk assessment tools and data. For example, in estimating the number of homes that would be identified as hazards at various environmental lead levels, the Agency relied upon data from the HUD National Survey. Obviously, when assessing the impacts of standards at lower environmental lead levels, estimates are more likely to be inaccurate due to the presence of outliers in the data than would be the case in the middle range of the data. Additionally, the Agency must consider the range of exposures over which its models relating environmental lead to blood lead can be expected to perform well and the sensitivity of those models to the data inputs. By considering at which points in its analyses the data and models are strongest and weakest, the Agency can identify where in its analyses the greatest levels of certainty exist. Consideration of these factors is described in section 3.b., which discusses the selection of the dust and soil hazard levels.

b. *Choosing the lowest candidate hazard standards.* While EPA is no longer considering the determination of what constitutes lead-contaminated dust or soil to be governed by different standards from those used in the determination of what constitutes dust or soil-lead hazards, the analysis used in the proposal to determine the contamination standards is still relevant to the consideration of options for the hazard standards. This is because the effect of choosing the proposed dust and soil lead contamination standards based on a 1 to 5% probability of an individual child's having blood lead levels exceeding 10 µg/dL was to establish the lowest candidate hazard standards. In the proposal, this was for dust 50 µg/ft^2 on uncarpeted floors and 250 µg/ft^2 for sills and for soil 400 ppm in the entire residential yard. Additional analysis, as noted below in discussion of the dust and soil hazard level determination, was applied to actually develop the hazard standards.

Furthermore, as noted above, the determination of which blood lead levels are truly hazardous (the blood lead level of concern) was the first scientific issue EPA had to decide in selecting dust and soil lead hazards.

Accordingly, EPA adopts as the basis determining the lowest candidate standards for the final dust and soil lead hazards the same policy basis used in the proposal for choosing dust and soil lead contamination levels--a 1 to 5% probability of a child's developing a blood lead level of 10 µg/dL.

The choice of 10 µg/dL is based on a significant body of scientific evidence, extensively cited in the preamble to the proposed rule, that shows that a number of significant health effects manifest themselves in the 10-15 µg/dL range. EPA hereby incorporates as the basis for its final decision on the blood lead concentration of concern all relevant discussions in the preamble to the proposed rule, particularly the discussion at 63 FR 30316-17. The Agency's decision is supported by past statements made by the Clean Air Science Advisory Committee and is consistent with Federal policy established by the CDCP and the recommendations of the National Academy of Sciences (NAS). The Agency wishes to emphasize, as it stated in the proposed rule, that this choice does not imply that 10 µg/dL is a threshold level. On the contrary, EPA maintains its position that there is no known threshold for lead. EPA decided not to use a level lower than 10 µg/dL because the evidence indicates that health effects at lower levels of exposure are less well substantiated, based on a limited number of children, and observation of subtle molecular changes that are not currently thought to be sufficiently significant to warrant national concern.

The choice of probability is based on the Agency's interpretation of the statute and the limits of EPA's analytical tools. The Agency rejected the lowest possible probability, which is zero. Even without lead-based paint and lead-contaminated soil and dust, there could be some small mathematical probability that a child could still have a blood-lead level equaling or exceeding 10 µg/dL. This is because other sources of exposure (e.g., air, water, diet, and background levels of lead) remain. Because under the statute EPA may only account for risks associated with paint, dust and soil, a zero exceedence probability would not make sense for this rule.

In addition, EPA's assessment for this rule indicates that, as a practical matter, in the context of establishing on a national level the initial candidate for the hazard level, the probabilities that given environmental levels of lead ''would result'' in blood lead levels of concern, 1% is not distinguishable from 5% in estimating risks from soil lead. This is because, within the context of the analyses for this rule, there was substantial overlap in estimates of risk from soil lead within the 1 to 5% risk range. This overlap is due to the uncertainty and variability related to EPA's analyses to associate low levels of lead in a specific environmental medium to blood-lead concentrations and limited data. For example, results from models used to relate environmental levels to blood lead levels vary depending upon what is assumed about the interrelationship between dust and soil. Also, in the performance characteristics analysis (explained below), the number of children was small, yielding similar results for a 1% exceedence as for a 5% exceedence. In effect, EPA is setting the exceedence probability as close to zero as it is able (within analytical limits of its analyses) for the effects of lead paint and lead in dust and soil.

In addition, given the data and analytical tools available to support this rulemaking, the Agency determined that, as a practical matter, 1% is not distinguishable from 5%. This overlap is due to the uncertainty and variability related to any effort to associate low levels of lead in a specific environmental medium to blood-lead concentrations and limited data. For example, in the performance characteristics analysis, the number of children was small, yielding similar results for a 1% exceedence as for a 5% exceedence. In effect, EPA is setting the exceedence probability as close to zero as it is able (within analytical limits of its analyses) for the effects of lead paint and lead in dust and soil.

At the other end of the range considered by EPA was an exceedence probability of 10%. With this distribution of risk, a child would have approximately a 2% chance of having a blood-lead concentration exceeding 15 µg/dL and a less than 1% chance of having a blood-lead concentration exceeding 20 µg/dL, the level at which CDC recommends medical intervention. In the proposal's discussion of the contamination standard, the Agency rejected this probability as presenting exceedingly high risks. For determination of a hazard level, they would also be excessively high. EPA believes it is inconsistent with the statute to establish a hazard standard at which significant numbers of children would need medical treatment.

c. *Basis for the dust and soil hazard standards.* As explained in the preamble to the proposal, EPA used cost-benefit balancing to establish a range of options for hazard standards. EPA then selected its preferred options based on consideration of relevant factors, including the assumptions and tools underlying EPA's analysis, health

protectiveness, cost, and the effect on the overall lead risk reduction program (63 FR at 30314–30315). The Agency refers the public to the proposal for the detailed discussion of its reasoning for choosing the approach to develop the hazard standards. EPA's approach for using cost benefit analysis is described in the proposed rule and is used for the final rule.

In this document, EPA wishes to highlight several points that merit special attention. First, the various modeling techniques used by EPA only established a range of possible answers upon which the Agency exercised its administrative judgement. EPA used its quantitative modeling as a tool to establish the boundaries of the Agency's inquiry, not as the sole basis for decisions. Because precise values cannot be assigned to risks (or costs), any cost-benefit balancing is appropriately used to help select an option within a range for the hazard standards. The Agency then selected its preferred options, from within the range bounded by the modeling results, based on consideration of relevant factors, including the weight of the evidence of harm, assumptions and tools that underlie EPA's analysis, as well as other factors, including health protectiveness and total costs.

To support the establishment of a range of options, EPA used a normative analysis which assumes that all hazards to young children will be identified and controlled. EPA adopted this approach not only in view of the obvious imprecision in its ability to estimate how the public will actually respond in terms of the number and scope of hazard control interventions that will be implemented in response to the standards, but also with the objective of allowing Agency decision-makers to compare costs and benefits. Thus, while the Agency can only estimate the theoretically possible costs and benefits associated with each option, not the actual costs and benefits, EPA is confident that the relative balance of costs and benefits estimated is unlikely to be very different from the relative balance of actual costs and benefits.

Finally, EPA wishes to emphasize that there is no set way to apply the balancing of costs and risk reduction. Where standards would require the high expenditure of resources, the level of risk reduction (considering both the toxicity of lead and the probabilities of exposure) and the strength of evidence should be correspondingly high. On the other hand, if the costs of standards are relatively low, the level of risk reduction and the strength of the evidence could be less compelling. As stated in the preamble to the proposed rule and as adopted in today's final rule, the determination on soil standards considers the fact that relatively high costs may be incurred to abate residential soils. Consequently, under a cost-benefit balancing concept, before selecting an option associated with high costs, EPA would want a greater measure of confidence that the standard would result in a higher level of risk reduction.

EPA recognizes that resources for abatement to address lead risks to children are often limited and that societies often have to set priorities. Therefore, establishing numerically low national standards could serve to dilute resources across more properties and communities instead of steering resources to address situations that present clearer, more certain risk. Along the same line of reasoning, the Agency believes that it is sound public policy for the hazard standard to embody a ''worst first'' approach that will aid in setting priorities to address the greatest lead risks promptly.

With respect to the paint component, data limitations prevented EPA from quantifying the costs and benefits of the options considered in the proposal (as well as for the final rule). Consequently, EPA's decisions with respect to the options for the paint component involved a more qualitative judgment on the part of the Agency in the proposal, as well as in the final rule. Later in this unit, EPA explains its decision for identifying what constitutes hazardous lead based paint.

2. *Technical analyses.* To support the development of the dust and soil hazard standards in this rule, EPA required tools to relate lead in the environment to blood-lead concentration. As described in the proposal to the proposed rule, EPA used several methods for this purpose: a mechanistic model that has been calibrated and validated with various empirical dataset and which simulates the body's response to lead exposure, and both modeling and non-modeling analyses of empirical data from the Rochester Lead in Dust Study. The mechanistic model is the Agency's Integrated Environmental Uptake and Biokinetic (IEUBK) model. The empirical data used in the modeling and non-modeling analysis to support this rule was obtained from a study of lead in Rochester, New York entitled ''Rochester Lead-in-Dust Study.'' The preamble to the proposed rule (63 FR 30315) contains a general overview of these tools. Given the uncertainties and limitations associated with any single approach, EPA decided that it would be helpful to obtain several perspectives (with different associated strengths and weaknesses) on the relationship between environmental lead and blood lead levels.

EPA thoroughly evaluated its choice of methods in response to public comments and all other information available to the Agency. EPA has concluded that it is appropriate to use the same methodology for its final decision. Based upon public comments and all other information in the rulemaking record, the Agency also recalculated the numerical results obtained for the proposed rule. These recalculations did result in some changes to the standards from those proposed, as is explained below.

a. *Initial candidate hazard levels*—i. *Dust.* For development of the proposed dust-lead contamination level (referred to as the level of concern) EPA used: A multimedia model based on the data from the Rochester Lead-in-Dust study and a performance characteristics analysis of the Rochester data. The reasons for using these models and their implementation is explained in the preamble to the proposed rule (63 FR at 30317–30319) in the Units titled ''c. Characterizing individual risk.'' and ''d. Dust analysis.'' For purposes of this analysis for determining the initial candidate levels for the final hazard standards, however, EPA judges it is appropriate to continue to use the same model, based on the same reasoning.

The multimedia model yielded the following results. The levels of lead in dust on floors associated with an individual child having from a 1 to 5% chance of having a blood-lead concentration equal to or exceeding 10 μg/dL range from near zero to 6.7 μg/ft^2. The range for dust loadings on window sills is from near zero to 74 μg/ft^2.

The performance characteristics analysis yielded the following results. For floors, dust-lead loadings ranged from 50 μg/ft^2 to 400 μg/ft^2. For interior window sills, dust-lead loadings ranged from 100 μg/ft^2 to 800 μg/ft^2. These ranges were significantly higher than the ranges yielded by the multimedia approach.

The performance characteristics analysis to support the determination that 1 to 5% of children would develop blood lead levels above 10 μg/dL remains unchanged for the analysis in this final rule. The results yielded by the multimedia model would put the environmental dust-lead levels at which 1-5% of children would develop blood lead levels above 10 μg/dL at near or below background levels and well below the residual levels that remain after homes have been well cleaned (i.e.,

the clearance levels). These results do not seem to make sense to the Agency since they imply that background levels in well cleaned homes would still be of concern from a risk perspective. Therefore, based upon public comments, the Agency reevaluated its analyses.

Based upon this reassessment, EPA decided to make some revisions to the way it applied the multimedia model so that its results would be more comparable to the performance characteristics analysis. This was accomplished by using the same set of parameters (average soil concentration, dust on floors and sills, and paint conditions) and the same subset of data from the Rochester Lead-in-Dust Study. Following these changes, the order of magnitude difference in results between the original multimedia model and the performance characteristics model virtually disappears. At 50 μg/ft^2, the performance characteristics shows a 7.5% risk of equaling or exceeding 10 μg/dL and the multimedia model shows a 5.34% risk. At 40 μg/ft^2, the performance characteristics shows a 5.1% risk of equaling or exceeding 10 μg/dL and the multimedia model shows a 5.30% risk. That is, under these analyses, floor dust levels at 40 μg/ft^2 correspond to 5% and less probability of blood lead levels exceeding 10 μg/dL. Thus, using the revised model, 40 μg/ft^2 is the standard that better meets the criteria spelled out in the Agency's proposal (less than 5% probability of exceeding 10 μg/dL). EPA provides a detailed description of this revised analysis in the ''Risk Analysis to Support Standards for Lead in Paint, Dust, and Soil: Supplemental Report.'' EPA accordingly has chosen 40 μg/ft^2 as the initial candidate level for the dust-lead hazard level in today's final rule.

ii. *Soil*. In the proposed rule, EPA set a ''level of concern'' based on the Agency's IEUBK model and a performance characteristics analysis of the Rochester data. The reasons for using these models and their implementation is explained in the preamble to the proposed rule (63 FR 30317, 30319) in the Units titled ''c. Characterizing individual risk'' and ''e. Soil Analysis.'' Under the IEUBK analysis soil-lead concentrations generally at or below 500 parts per million (ppm) would result in a 1 to 5% probability that a child will have a blood-lead concentration that equals or exceeds 10 μg/dL. The performance characteristics analysis for soil ranged from 200 ppm to 1,500 ppm correlated with 1 to 5% of children with elevated blood lead levels exceeding 10--μg/dL. EPA chose 400 ppm as the proposed soil lead contamination level. EPA adopts that same level as the initial candidate soil hazard standard for the same reasons as provided in the preamble to the proposed rule for choosing 400 ppm as the soil contamination level.

3. *Dust and soil hazard levels*. The analyses to support selection of the dust and soil hazard levels included evaluation of the nation-wide reduction in risk that could potentially result from a set of hazard standards. EPA measured the change in risk reduction in terms of an estimated change in the national blood-lead distribution, equated this change to reductions in several adverse public health outcomes (e.g., IQ point loss), assigned a value to these reductions, and compared these public health benefits to the costs of hazard intervention.

a. *Methodology*. EPA finds no reason to change its methodology of using a normative cost-benefit analysis for developing dust-lead and soil-lead hazards. The Agency, accordingly, adopts the reasoning set forth in the preamble to the proposed rule for conducting this analysis. The general overview of the cost-benefit analysis and its use in decisionmaking is provided in the preamble to the proposal (63 FR at 30319–30320) in the introductory paragraphs to the section entitled ''2. Dust-lead and soil-lead hazard standards''.

The methodology for estimating risk reduction is found in the section entitled, ''a. Estimating risk reduction.'' (63 FR 30320) and, partially, in the section entitled ''b. Estimating costs and benefits.'' (63 FR 30321). Methodology for estimating the monetary value to be assigned to the value of risk reduction that may be achieved by actions taken in response to the hazard standards is found in the section entitled ''b. Estimating costs and benefits.'' (63 FR at 30320–30321). Determination of the costs of actions that may be taken to reduce risk is in the same section at 30321-22 and in two paragraphs at 63 FR 30325 in the section entitled ''c. Results.'' The limitations, qualifications and uncertainties that affect both the estimates of benefits and costs are found at 63 FR 30322–30323 in the section entitled ''b. Estimating costs and benefits.''

The Risk Assessment was designed to estimate the declines in children's blood lead levels that would result if abatement and other response actions were taken in housing units that exceeded candidate standards for paint, dust, and soil. While certain details of the analysis are complex, the basic approach is straightforward. First, a baseline of environmental lead and blood lead levels was established. These represent the ''pre-403'' conditions.

For the pre-403 environmental lead levels, the Agency used the Department of Housing and Urban Development's National Survey of Lead-Based Paint in Housing (the HUD Survey). Conducted in 1989-1990, the HUD Survey measured the extent and condition of lead-based paint in housing, the amount of lead in dust within the housing, and the amount of lead in soil surrounding the housing. For the pre-403 blood lead levels, the Agency used Phase 2 of the third National Health and Nutrition Examination Survey (NHANES III). Conducted by the Centers for Disease Control and Prevention in 1991-1994, NHANES III included measurements of children's blood-lead levels.

Next, the Agency estimated the reduction in environmental lead levels that would result if abatements or other responses were performed in housing units that failed candidate standards for paint, dust, and soil. These levels represent the ''post-403'' environmental lead levels and rely upon estimates of the effectiveness and duration of the response actions.

The Agency then modeled the blood lead levels that would correspond to the pre- and post-403 environmental lead levels. This allowed an estimation the blood-lead reduction that would result from the standards (i.e., the difference in the blood lead levels from the pre-403 environmental levels to the post-403 environmental levels). Here, the Agency used two different models the Integrated Exposure Uptake Biokinetic (IEUBK) Model and an empirical model that was based upon the results of the Rochester Lead in Dust Study. Consequently, there are two different estimates of the blood-lead changes that would result from the 403 standards, one based upon each model. Finally, the two estimates of blood-lead changes were re-scaled by applying the pre-403 blood-lead levels in NHANES III. EPA repeated this process for each set of standards under consideration.

The two models of risk assessment were incorporated into the economic benefit-cost framework to generate net benefit estimates for the various candidate hazard standards. EPA wishes to emphasize that it is more important to consider the net benefit estimates relative to each other rather than their actual numerical value for the various candidate hazard standards. In order to apply these models in this national analysis, the models relating environmental lead to blood lead could not reflect the consideration of site-specific data to the extent that would be sought when they are applied locally.

Also, the Agency recognizes that the costs and benefits associated with the normative analysis are likely to overstate the actual costs and benefits associated with the standards since it is likely that not everyone will follow the rule recommendations and, to the extent they do not, benefits and costs would both be lower. This is not of great concern because the objective of this analysis is to provide EPA with a tool to compare options in terms of relative costs and benefits of each option, not to develop precise absolute estimates of costs and benefits.

Despite the limitations and uncertainties of the analysis, the results for options within each model can be compared. The limitations may affect the estimates of absolute costs and benefits, but these limitations should have similar effects on the estimates for each option. Additional discussion of how to interpret the results of the normative cost-benefit analysis is provided in the preamble to the proposed rule (63 FR 30323) at the beginning of the Unit entitled ''c. Results.''

b. *Results.* The results of the analysis, under each model, to determine dust-lead and soil-lead hazards for the proposed rule are found in the preamble to the proposed rule (63 FR at 30323–30325). The results of the analysis after the reevaluation for the final rule are presented in this section. The analysis' computation of net benefits is the difference between the total benefits estimate and the total costs estimate. Net benefits are an indicator of the societal gains from hazard controls. While the rule, in and of itself, does not impose a requirement to abate the hazards, for purposes of its risk analysis for this rule, EPA has assumed that abatement will be undertaken in all homes that exceed the levels when a child is born. This analysis does not account for the costs and benefits associated with child-occupied facilities because of the lack of available data and resources.

While the Agency has assumed that the remediation response to the presence of a paint, dust or soil lead hazard is abatement (e.g., removal or permanent covering for soil) for purposes of its analyses, it should not be concluded that the Agency has identified abatement as the only viable response to paint, soil or dust hazards. The Agency believes that well-designed and well-managed programs of interim controls can achieve significant reductions in hazards and, particularly for soil hazards, could be less expensive than removal.

As noted previously in this preamble, in performing its analyses for this rule, the Agency could not quantitatively compare interim control strategies with abatement strategies because there are only limited data available on the effectiveness of interim controls over extended periods of time, and those data which are available are not suitable for quantitative comparisons with abatements. Nevertheless, experience with interim control programs is increasing and certain organizations, particularly public health and housing agencies, believe they have been able to develop effective programs for interim controls which achieve virtually the same degree of risk reduction as do abatement programs, but at much reduced cost. EPA believes that public and private organizations should evaluate both interim control and abatement strategies in determining the most effective course of action.

Therefore, while EPA does not have the authority under this statute to mandate any particular remediation action for lead-based paint hazards, it recommends strongly that some action be initiated--interim controls or abatement--if lead levels exceed the hazard standards. Morever, if bare soil-lead levels are below the hazard standard in non-play areas, the Agency recommends that organizations and individuals at least consider some action in bare soil in those areas if there is a concern that children under the age of 6 might spend substantial time in such areas, or there is concern that the bare soils in such areas may contribute to hazardous lead levels in the dwelling, or in the play area.

The IEUBK-based analysis and the Empirical-model-based analysis are only used to calculate the benefits of the various options. Costs are calculated in the same manner for both models. Total costs increase as options become increasingly stringent and are mainly a function of unit costs (costs for a single abatement) and the number of homes affected. Unit costs for dust are the same whenever a dust lead hazard is present. For soil, unit costs vary depending on the part of the yard being addressed by the abatement (e.g., dripline, mid-yard, play-area) and on whether the removed soil has to be managed as hazardous waste under regulations under the Resource Conservation and Recovery Act (RCRA). The unit cost is lower for lower soil-lead levels (below 2,000 ppm) because it is expected that the removed soil would not have to be managed as hazardous waste.

In the analysis for the proposed rule, unit costs for dust abatement were $ 391 for single-family homes and $ 262 for multi-family units (63 FR 30324). The preamble to the proposed rule (63 FR 30322) included the following complete range of unit costs for soil removal and other control actions as follows:

TABLE 1.—HAZARD EVALUATION AND CONTROL COSTS (PER ACTIVITY IN 1995 DOLLARS)

Activity	Single Family	Multi-family (per unit)
Risk assessment	456	235
Interior paint repair	437	437
Interior paint abatement	6,587	4,687
Exterior paint repair	807	182
Exterior paint abatement	5,706	2,275
Dust cleaning	391	262
Soil removal (dripline; nonhazardous waste)	2,046	399
Soil removal (mid-yard; nonhazardous waste)	7,878	777
Soil removal (both areas; nonhazardous waste)	9,008	901

TABLE 1.—HAZARD EVALUATION AND CONTROL COSTS (PER ACTIVITY IN 1995 DOLLARS)—Continued

Activity	Single Family	Multi-family (per unit)
Soil removal (dripline; hazardous waste)	3,443	541
Soil removal (mid-yard; hazardous waste)	16,486	1,351
Soil removal (both areas; hazardous waste)	19,013	1,617
Soil removal (play area, non-hazardous waste)	1,460	314
Soil removal (play area, hazardous waste)	2,129	359

It is important to note that, as printed in the proposal, this table contained a typographical error with respect to the cost of exterior paint abatement in single-family housing. This error was identified and corrected in a **Federal Register** document published on December 18, 1998 (63 FR 70087) (FRL–6048–3).

Total costs for the various options considered are found in Tables 4, 5, 6, and 7 of the proposal (63 FR at 30324–30325). Similar tables, although slightly revised as is described later in this section, are presented as Tables 7–A1 through 7–A4 in Appendix 7 of the Economic Analysis of the TSCA section 403 Lead-based Paint Hazard Standards Final Rule (December 2000) (Economic Analysis) (Ref. 14). As in the proposal, however, these tables do not include estimated costs or benefits of paint interventions, or any testing or risk assessment costs. Since only a single standard was considered for paint interventions, associated costs and benefits are omitted from the tables to permit a clearer presentation of the incremental changes in costs and benefits that are associated with changes in standards for the option considered. The Agency also omits testing and risk assessment costs in the tables below for a similar reason. Finally, in order to observe the effects of intervention in each medium separately, EPA held lead levels in all other media constant at baseline levels, which are based on the HUD National Survey data. In tables 7A-3 and 7A-4 for the estimated costs and benefits for soil-lead hazard standard, independent dust and paint interventions are assumed not to occur. Some dust interventions that are triggered by soil abatements are incorporated in these two tables.

The units of benefit and the value being assigned to them are presented in Table 2 below.

TABLE 2.—SUMMARY OF BENEFITS ANALYSIS ESTIMATE

Type of Effect	Description	Estimate	Source
Effect of a Single Point Reduction in IQ	Sum of the direct and indirect effects on the percent of earnings lost (2.379%) and express the effect in terms of the present value of average lifetime earnings	$9,360 in 1995 dollars	Product of the estimate of the present value of average lifetime earnings based on U.S. Department of Commerce ($366,021 (1992 $)) and the assumed percentage loss of earnings from a single point reduction in IQ of 2.379% (Salkever 1995)
Cost of Additional Education	Sum of the direct costs ($316) and opportunity costs ($627) of additional education	$1,014 in 1995 dollars	Sum of the estimate of the direct and opportunity costs of additional education based on U.S. Department of Education (1993) data
Total Effect of a Single Point Reduction in IQ	Subtract the costs of additional education from the effects on earnings lost	$8,346 in 1995 dollars	Accounting for the cost of additional education was based on Salkever (1995)
Special Education (IQ less than 70 points)	Cost of special education beginning at age 7 and ending at age 18	$53,836 in 1995 dollars	Kakalik et al. (1981) estimate annual incremental regular classroom costs of $6,458 in 1995 dollars for special education. This estimate is the discounted value of such costs for age 7 through 18.
Compensatory Education (Blood lead greater than 20)	Cost of compensatory education beginning at age 7 and ending at age 9	$15,298 in 1995 dollars	Kakalik et al. (1981) estimate annual incremental regular classroom costs of $6,458 in 1995 dollars for compensatory education. This estimate is the discounted value of such costs for age 7 through 9.
Medical Intervention (for several blood lead ranges)	Cost of blood lead screening and medical intervention for children less than six years old (by blood lead Risk Group)	Risk Group[1] I:$58; R.G. IIA: $70; R.G. IIA: $227; R.G. IIA: $417; R.G. IIA: $678; R.G. IIA: $9843; R.G. IIA: $9843	Recommendations and actual practice based on information from CDC (1991), AAP (1995), and medical practitioners. These estimates are the discounted costs per newborn associated with each blood lead Risk Group.

[1](All in $1995)

Calculations for the IEUBK-based analysis for a range of dust hazard options for floor dust and the soil hazard standard options are presented in the economic analysis (Ref 14). Discussion of the calculations is found at 63 FR 30323-25. The dust values for 40 μg/ft² will be discussed later in this preamble. Finally, the units of benefit and the value being assigned to them in these analyses are presented in Table 2.

In summary, total benefits increase as options become increasingly stringent, ranging from $ 50 billion to $ 88 billion for dust and from $ 16 billion to $ 145 billion for soil. As discussed in the Economic Analysis, the results presented for soil account for the fact that soil interventions (excluding those in play areas only) include dust interventions following the removal and replacement of soil, and thus incorporate the costs and benefits associated with dust interventions in addition to the costs and benefits associated with the soil abatement itself. Benefits increase at an increasing rate because, as dust and soil-lead levels decline, the number of homes at given environmental lead levels increases more quickly. For example, moving from a soil standard of 5,000 ppm to 4,500 ppm increases the number of homes exceeding the standard from about 600,000 to about 700,000 (an increase of about 100,000 housing units), while moving from 1,000 ppm to 500 ppm increases the number of homes exceeding the standard from about 6 million to 12 million (an increase of about 6 million housing units).

Because total benefits increase at a faster rate than total costs, net benefits also increase as options become increasingly stringent, ranging from $ 42 billion to $ 69 billion for dust and $ 13 billion to $ 103 billion for soil. The increase in net benefits is relatively constant as the dust standards become more stringent. For soil, net benefits increase slowly from 5,000 ppm to 3,000 ppm and increase more quickly from 3,000 ppm to 2,000 ppm and from 1,200 to 500 ppm. Net benefits increase because total benefits are increasing at a faster rate than total costs.

It is important to note that the above analyses do not take into account lead levels in other media. Controlling for other contributors to blood lead presents a different picture of the net benefits that result from moving to a more stringent standard.

Under the Empirical-model for floor dust, total benefits increase as options become increasingly stringent, ranging from $ 27 billion to $ 36 billion. For sill dust over the range of candidate standards that were considered, net benefits are in the maximum range at 250 μg/ft² and are slightly higher with floor dust standards of 50 μg/ft² as compared to 100 μg/ft². As is the case in the IEUBK model-based analysis, the rate at which benefits increase rises as the stringency of the options increase, because more homes are affected (and more children are protected). The rate at which benefits increase, however, is tempered somewhat because the relationship between dust and soil-lead and blood lead remains relatively constant across the range of options considered. The increasing number of children protected by more stringent standards is counter balanced by decreasing risk reduction predicted for children living in homes with low dust and soil-lead levels. That is, there are smaller changes in blood lead because there are smaller changes in environmental-lead between baseline dust-lead levels and post-intervention levels.

Of the combinations of dust standard options evaluated in the proposal, net benefits were relatively constant for all the combinations except the most and least stringent (floor = 50 μg/ft² with sill = 100 μg/ft² and floor = 100 μg/ft² with sill = 1,000 μg/ft², respectively). For the other options considered, benefits and costs increase at approximately the same rate, resulting in little change in net benefits. Specifically, the combinations resulted in net benefits of around $ 20 billion, which is also the case when a floor standard of 40 μg/ft² is considered.

Net benefits for soil range from $ -7 billion to $ 2 billion, approaching maximum levels near 5,000 ppm and 2,000 ppm. Below 2,000 ppm, net benefits decrease because total benefits increase at a slower rate than total costs. The increased number of children protected at more stringent standards is offset by a smaller predicted reduction in risk at lower environmental levels.

4. *Selection of the standards and other Agency decisions.* This section of the preamble presents the explanation of EPA's decisions regarding the standards for dust and soil lead hazard and paint-lead hazard standards.As part of the discussion of the Agency's decisions for each media, EPA is also presenting its decisions on related issues including sampling location and interpretation. The dust section will also include a discussion of the dust clearance standards, and the soil section will include EPA's decision regarding management of soils removed during abatement.

The clearance standards for dust, interpretation of composite clearance samples, soil management practices, and sampling location requirements are not being issued under authority of section 403 of TSCA, but under the work practice standards of section 402. Therefore, the legal reasoning, policy decisions, and technical analyses explained above do not have direct applicability to their promulgation. EPA is presenting these issues in this unit for public convenience, in order to keep all its decisions regarding each medium in one place in this preamble.

a. *Dust*—i. *Dust-lead hazard standards.* EPA has decided to adopt a dust-lead hazard standard 40 μg/ft² for floors and 250 μg/ft² for interior window sills) in the final rule. The floor standard is changed somewhat from the proposal but the window sill standard remains the same as for the proposal.

According to the Empirical model-based analysis for the proposal, the results of which are summarized in Table 6 of the proposed rule, four of six combinations of options for floor and window sill standards have net benefits in the maximum range (i.e., $ 21 to $ 22 billion). One combination (100 μg/ft² for floors, 1,000 μg/ft² for sills) provides significantly less risk reduction relative to cost; and one combination (50 μg/ft² for floors, 100 μg/ft² for sills) provides little additional benefit but costs increase significantly. Incremental benefits are less than one third the incremental costs and an additional 11 million homes would fall under the standard. EPA, therefore, considers that this lower standard for sills is associated with increased costs without commensurate attendant benefits.

Of the four combinations considered in the proposed rule, the 50/250 μg/ft² standard was found to be the most protective in terms of the amount of risk reduction yielded. The other three options, though less costly, also provided less risk reduction. The decrease in both costs and benefits as the combination of floor and sill options become less stringent were roughly the same (between $5 billion and $6 billion), resulting in little change in net benefits.

EPA's decision on the proposed floor standard was further supported by the results of the IEUBK model-based normative analysis, summarized in Table 4 of the preamble to the proposed rule, which showed that the net benefits for the proposed floor standard were greater than those for a less stringent standard; net benefits estimated by this analysis increased from $ 48 billion for 100 μg/ft² to $ 61 billion for the proposed 50 μg/ft² standard.

EPA reiterates that this normative cost-benefit analysis has been undertaken for comparative purposes

only to evaluate the hazard standards on a relative basis. However it does not mean to imply that billions of dollars will be spent on lead dust cleanup because the responses projected in the cost estimates may not necessarily reflect the behavior of residents and building owners over 50 years. These costs also reflect some extremely conservative assumptions, such assuming that all yards are potentially affected even if they actually contain no bare soil. These costs are put into better perspective when it is understood that the cost per residence of dust cleaning is less than $600 per affected residence over a 50–year period in 1995 dollars. In making this decision, EPA recognizes that the proposed standard could result in dust hazard interventions in perhaps as many as 20 million homes. Although this is a very large number of homes, the cost of intensive dust cleaning is relatively low for individual residences.

EPA decided to propose the 50 μg/ft² and 250 μg/ft² standards respectively for floors and sills because the Agency preferred to select the most protective of the four combinations.

In the proposal, the Agency did not consider a floor standard option less than 50 μg/ft² because, in its risk analysis, EPA's best estimate was that the post-intervention dust-lead loading would be the lower of the pre-intervention dust-loading or 40 μg/ft². This was the Agency's best estimate of dust levels that would remain after controlling sources of lead and thoroughly cleaning the residence. It was based on an analysis of data from several abatement studies which is more fully discussed in Chapter 6 of the Agency's risk analysis (Risk Analysis to Support Standards for Lead in Paint, Dust, and Soil, EPA 747–R–97–3006, June 1998) (Ref. 12). in the record for the proposed rule. In light of this estimate, EPA found it would be impractical to set the standard for floors lower than 40 μg/ft² because little or no risk reduction would likely to be achieved for homes that had dust-lead loadings at or below 40 μg/ft².

In the preamble to the proposed rule, EPA stated that, if new data were to become available before promulgation of the final rule that show that even lower post-intervention dust-lead loadings could be achieved, EPA would consider establishing a more stringent dust-lead hazard standard. A number of comments were submitted claiming that cleanup could be achieved below 40 μg/ft². Of particular relevance were comments from HUD stating that, in its experience, cleaning to levels below 40 μg/ft² was typically achieved as evidenced by its Grantees program. In fact, since the proposal of this rule, HUD has promulgated a 40 μg/ft² standard for floors in its 1012/1013 regulations. Since EPA's basis for not considering a standard less than 50 μg/ft² was based upon its understanding of the effectiveness of cleaning and, based upon the data provided by HUD in its comments, it is now clear that a 40 μg/ft² standard is achievable, the Agency is establishing 40 μg/ft² as the dust-lead hazard standard for floors. The Agency believes that this is consistent with the approach taken in its proposal namely, that the floor-dust hazard standard should be at the lower end of the range where risk reduction is possible. Further, when considered in terms of its cost-benefit analysis, EPA found that indeed positive net benefits resulted for the 40 μg/ft² hazard standard. In fact, as compared to the proposed standard of 50 μg/ft² with a sill dust standard of 250 μg/ft² (see Tables 2 and 4), net benefits are somewhat higher under the IEUBK model-based analysis and approximately the same under the Empirical model-based analysis.

EPA does not believe it is appropriate to set a dust-lead hazard below this level for the additional reason that such a level would significantly increase the number of homes identified as lead hazards and would not likely identify more truly hazardous environments. This is based on the fact that these lower levels would identify significantly more than the approximately 22 million homes that are identified as having dust-lead hazards under the 40 μg/ft² standard. In view of the fact that there are far less children in the population with elevated blood lead levels, EPA has to question modeling results that would suggest such lower levels.

ii. *Carpeted floors.* In contrast to the proposed standards that only applied to uncarpeted floors, EPA has decided to include carpeted floors in the dust-lead hazard standard, and the clearance standards. EPA's reasoning is explained herein.

The Agency received substantial comment on the issue of the floor dust standard, and its proposed limitation to uncarpeted floors. As discussed in the preamble for the proposed rule (63 FR 30336), EPA did not include dust standards for carpeted floors because the Agency was unaware of adequate data that could be used to establish a statistical relationship between dust lead on carpeted floors and children's blood-lead concentrations. In the absence of such relationship, EPA felt it could not estimate the level of risk and risk reduction that would be associated with various levels of dust-lead in carpeted floors. Furthermore, EPA did not believe it had adequate data on the effectiveness of carpet cleaning that would be needed to establish a dust clearance level for carpeted floors. EPA did state that it planned to analyze expeditiously any newly available data to establish dust standards on carpeted floors and to amend the regulations to add standards for carpeted floors.

EPA, however, acknowledged that the lack of standards for carpeted floors was a significant limitation of the proposal. Accordingly, the Agency requested comment on the impact of not including standards for carpeted floors and indicated it would be interested in any information or data that would help it establish such standards.

Almost all comments on this issue disagreed with EPA's decision not to set carpet standards, even though many recognized that the lack of data on hazardous levels of lead in carpets makes it difficult for EPA to establish a dust-lead standard for carpeted floors. However, by excluding carpet dust from the dust hazard standard EPA will cause excessive amounts of lead to be ignored during dust-lead control activities. Many children who live in homes with wall-to-wall carpeting will remain unprotected from floor dust-lead hazards. Using data from the 1997 American Housing Survey, EPA estimates that approximately 54 million housing units built prior to 1978 contain some wall-to-wall carpeting. Of these units, wall-to-wall carpeting is found in a living room in approximately 47 million units and in a bedroom in approximately 46 million units (i.e., rooms in which children reside and play most frequently.

A number of comments pointed out the unintended consequences of not having a dust-lead standard for carpets. Contractors complained that, because abatement requires quality control standards in order to be properly executed, many contractors will refuse to work in rooms where there is no standard on which they can fall back to show they have done their work correctly. This could raise liability issues because there would be no standard to determine whether it is safe for a family to return to a home after a lead cleanup. Not having a carpet standard could create the notion that, if carpet remains, there is no hazard on the floors and the carpeted floor can be ignored. Further, a property owner could avoid having to meet clearance levels for lead dust on floors simply by laying carpet.

In view of the substantial loophole that could be created in the absence of a standard for carpeted floors, many comments recommended that EPA

should maintain one standard for all floors until research can be done that supports a different standard for carpeted floors. The Agency is persuaded by the comments that the absence of any standard at this time would potentially lead to significant exposures for children, and that some standard is necessary at this time.

In response to these concerns, the Agency has reviewed the information submitted by commenters and other information in its rulemaking record, including the data base supporting the floor dust-lead standard. EPA agrees with the comments that the huge potential loophole created by not having a carpet standard could affect large numbers of children and would be inappropriate. It is known that carpeting can be a dust reservoir with significant amounts of lead. In addition, the Agency believes that its rulemaking record supports setting a carpet standard that is the same as the standard for bare floors.

Specifically, EPA finds that the following information supports setting a carpet standard that is the same as the bare floor standard. First, EPA agrees with the comments, particularly with respect to the fact that substantial amounts of children would remain unprotected by not having a carpet standard and that the consequences are harmful to public health.

With respect to data, EPA has examined its analysis that supported the dust-lead hazard standard. That analysis not only supports the standard for bare floors, but also the same one for carpeted floors. This is because the data that was used as input to its models did not distinguish between bare floors and carpeted floors. That is, the Agency's risk analysis, its analysis of risk reduction that could be achieved through cleanup, and the cost-benefit analysis for floors evaluated both carpeted and uncarpeted floors. EPA cannot definitively state that, in fact, all factors will be the same for both carpeted and uncarpeted floors, but sufficient evidence exists to establish a carpet standard. This is based upon considering the potential loophole that could exist in the absence of a carpet standard and the fact that some correlation exists between carpeted and non-carpeted floors.

The correlation between carpeted and non-carpeted floors is supported by data in the rulemaking record, as well as data submitted by HUD in comment. These data include the Rochester (NY) Lead-in-Dust study and the pre-intervention, evaluation phase of the HUD Lead-Based Paint Hazard Control Grant (''HUD Grantees'') Program (data collected through September 1997), both of which appear in the record for this rulemaking and are described in the Risk Analysis for the proposed rule. The Rochester Study shows a significant correlation between dust lead in carpets and children's blood lead. Further, the study showed that the percentage of children with blood-lead levels above 10 μg/dL were nearly the same with carpeted and uncarpeted floors (19.8 and 18%, respectively). This correlation supports setting at least the same standard for carpeted and non-carpeted floors. In addition, data from the HUD Grantees indicate that grantees were able to reduce dust-lead loadings in carpets, although the data are limited by the fact that grantees were working with higher clearance standards (80 - 200 μg/ft^2 instead of 40 μg/ft^2). Nevertheless, the fact is that the identical cleaning techniques were used, regardless of the clearance standard. Finally, there are no scientific data available demonstrating that carpeted floors pose different risks to children than any other type of flooring.

Accordingly, EPA's dust-lead, hazard and clearance standards apply to all floors. This will ensure that children are protected from dust hazards on all types of floors until future rulemakings can more definitively evaluate the need for different carpet standards.

iii. *Sampling requirements related to assessing dust-lead hazards.* EPA is adopting the sampling location (63 FR 30342) and interpretation (63 FR 30339—30340) requirements based on the rationale in the proposed rule. This regulation amends the work practice standards for risk assessments at 40 CFR 745.227 to require risk assessors, for purposes of hazard assessment, to take samples from floors and interior window sills. This regulation also amends the work practice standards to require risk assessors to make the dust-lead hazard determination by comparing the average of wipe sample results, weighted by the number of subsamples in each sample to the hazard standard for the appropriate surface (i.e., floors, sills) For multifamily properties, the risk assessor will determine that unsampled units of particular type of surface (i.e., floors, sills) constitute a hazard if at least one sampled unit is determined to be a hazard. Unsampled common areas are presumed to contain a lead-based hazard if at least one sampled common area of a similar type contains a lead-based hazard.

iv. *Dust clearance standards.* EPA is explaining in this section its reasoning for establishing clearance standards for cleanup of lead dust hazards and work practice standards for interpreting composite samples for clearance purposes.

Clearance standards are used by certified individuals to evaluate the adequacy of the cleanup performed in residences at the completion of abatement. According to the practices prescribed at 40 CFR 745.227, a certified risk assessor or inspector must collect dust samples and have them analyzed by an EPA-recognized laboratory following the cleanup to assure that the cleanup reduces dust-lead levels to prescribed ''clearance'' levels. If the clearance levels are not met, the cleanup and testing process must be repeated until the clearance standards are met. Although clearance testing is not required following implementation of interim controls (e.g., paint repair), the Agency strongly recommends such testing to ensure that the residence has been adequately cleaned.

With respect to composite sampling, the work practice standards at 40 CFR 745.227 do not differentiate between single surface samples and composite samples for determining compliance with clearance standards. EPA recognizes that because composite samples provide an average level of lead, low values on some surfaces may mask the presence of lead levels that exceed clearance standards on other surfaces. EPA continues to believe, however, that composite sampling is a useful tool for risk assessment and clearance and wishes to preserve its use under the regulations, the Agency proposed a method to remedy this problem and discussed various related issues in the preamble to the proposal (63 FR 30342).

A. Clearance standards for floors and sills. The final regulation contains clearance standards for floors and interior window sills of 40 μg/ft^2 and 250 μg/ft^2 respectively. This change from 50 μg/ft^2 to 40 μg/ft^2 accounts for the Agency's decisions to include standards for carpets as well as bare floors and to lower the dust lead hazard standard, as discussed earlier in this preamble.

The preamble to the proposed rule (63 FR 30341) discusses the statutory requirements applicable to clearance standards in TSCA section 402. On the same page, EPA provides the reasoning supporting the Agency's decision to use the same level to define clearance standards for dust as is used to define dust hazard standards for floors and interior window sills. This section of the proposal also explains how the Agency considered available field data documenting experience with the HUD cleaning protocol and decided to propose clearance standards that are the

same as the dust-lead hazard standard. These portions of the preamble to the proposed rule are adopted as support for the final clearance standards in this rule.

B. Clearance standard for window troughs. For window troughs, where EPA is not issuing a hazard standard, the Agency has decided to issue a clearance standard of 400 μg/ft². This is a change from the proposal, where EPA proposed to adopt the then-existing clearance standard of 800 μg/ft² from HUD's guidance.

The decision is based on EPA's consideration of public comments, and other information available to the Agency, which suggested that 400 μg/ft² is an appropriate clearance standard for window troughs. In the proposal, EPA used the current HUD clearance level for troughs (800 μg/ft²). As a result of the public comments, EPA revisited the data from the Agency's clearance evaluation, which clearly demonstrates that the 400 μg/ft² level is achievable without a major increase in burden. In six of the eight studies the pass rate for 400 μg/ft² after one trough clearance test ranged from 80.3% to 93.6%. The corresponding range for 800 μg/ft² is 88.4% to 96.6%. Two of the studies had significantly lower pass rates at 400 μg/ft² (30.6% and 53%). These studies, however, also had lower significantly lower pass rates at 800 μg/ft² (43.5% and 62.9%).

C. Sampling location and interpretation of composite dust samples. EPA is adopting the amendments to the sampling location requirements in the abatement work practice standards at 40 CFR 745.227 discussed in the proposed rule. This amendment changes sampling locations from uncarpeted floors and windows to all floors, interior window sills, and window troughs. This change is needed because the EPA is establishing clearance standards for all floors, including carpeted floors, and specific window surfaces.

To remedy the problem that composite samples may mask the presence of lead levels that exceed clearance standards, EPA proposed to require a risk assessor to divide the clearance standard by the number of subsamples in the composite. For example, if a composite floor sample of 50 μg/ft² contained four subsamples, the risk assessor would compare the loading from the composite sample to 12.5 μg/ft² (i.e., the proposed floor clearance standard divided by four). Using this approach, it was mathematically impossible for the composite to pass when any single subsample exceeds the 50 μg/ft² proposed clearance standard for floors. It would have, however, introduced the possibility of a composite sample failing clearance even if all the subsamples would have passed clearance individually (i.e., false failure), leading to additional clean up activities that would not have been necessary. At the time of the proposal EPA decided that this method would provide the best balance of safety, effectiveness, and reliability (63 FR 30342). EPA specifically asked for comment on this approach.

Commenters objected to this approach for several reasons. The most persuasive is that this approach would create a significant disincentive for risk assessors to use composite testing. HUD specifically referred to a study by Scott Clark and Paul Succop which showed that a better approach would be to compare the composite sample to the clearance levels divided by half the number of subsamples. Clark's and Succop's data shows that this approach produces an equivalent rate of passing clearance as single surface sampling.

Upon review of this study, EPA has decided to adopt this approach and is amending the work practice standards at 40 CFR 745.227 accordingly. Although the Agency prefers single surface sampling, it does not want to create a disincentive to conduct composite testing since in some circumstances it can save time and money. By selecting an approach that judges composite samples and single surface samples in an equivalent manner, EPA is removing the disincentive that the proposed approach would have created.

b. *Soil.* This section of the preamble presents EPA's decisions regarding the soil lead hazard standards. It addresses the soil-lead hazard standards for children's play areas and the remainder of the yard, and management controls for soil removed during an abatement:

i. *Soil hazard standard.* For the final regulation, EPA has selected 400 ppm in bare soil as the hazard standard for children's play areas and is an average of 1,200 ppm as the soil-lead hazard standard for the remainder of the yard. EPA's decision is a change from the proposed standard of 2,000 ppm as a yard-wide standard.

EPA's reasoning in support of the 2,000 ppm yard-wide standard is explained in the preamble to the proposed rule (63 FR at 30328–30330). To determine the final soil hazard, EPA uses the same underlying legal and policy rationale in the proposal. The Agency, however, now believes it is more protective of children and still consistent with the legal and policy bases to establish a lower level that focuses on children's play areas, as well as a lower level for the remainder of the yard.

EPA did not identify new information that has a significant bearing on the decisions needed for this rule and indeed is using the same references cited in support of the proposed soil hazard standard, to support this final decision. Comments on the proposal that questioned whether the proposed standard would be adequately protective of children, however, did cause the Agency to rethink its approach in reviewing the results of the analysis and the assessment of the available options. During this reevaluation of the options, EPA considered all options from 400 ppm to 5,000 ppm and selected the most protective option that could be supported by the analysis. This section presents EPA's rationale for selecting 400 ppm for children's play areas and 1,200 ppm for the remainder of the yard as the hazard standards and for not choosing the other options. Detailed responses to comments on all the options are found in the RTC document.

In order for the public to understand EPA's reasoning for the final soil hazard levels, the Agency believes it is necessary to review its reasons for not selecting the lowest and highest levels under consideration (400 and 5,000 ppm yard-wide averages, respectively), the reasons for proposing 2, 000 ppm instead of 1,200 ppm as yard-wide standards, and the reasons for choosing 1,200 ppm in the nonplay areas as the final soil hazard standard. This discussion will also show where the final analysis is consistent with the proposal and where divergence from the proposed reasoning is appropriate.

The proposal explained that, to arrive at a soil-lead hazard level, EPA sought to determine, with consideration of the uncertainty of the scientific evidence regarding environmental lead levels at which health effects would result, those conditions for which the Agency had sufficient confidence in the likelihood of harm that abatement seemed warranted to achieve the associated level of risk reduction. This is the method EPA has used to arrive at standards for both dust and soil. The Agency has determined that this is an appropriate way under the statute to determine whether a dust or soil lead ''would result'' in adverse human health effects. EPA has followed a similar approach in examining the final decision, although it has reached a different conclusion with respect to choosing the levels.

In the proposal, EPA rejected options for both higher and lower soil lead levels for a number of reasons. While, at

the time the Agency was only considering a yard-wide standard, those reasons are still relevant to today's final decision. However, the Agency's reasons for not selecting the extremes of either 400 ppm and 5,000 ppm, as a yard-wide standard, were of a more serious nature than its reasons for not choosing of 1,200 ppm. For this final rule, EPA reaffirms the reasoning in the proposal for not selecting the 400 ppm and 5,000 ppm standards, as yard-wide standards, with additional explanations noted below.

With respect to not choosing the 400 ppm level as a yard-wide standard, EPA acknowledged in the preamble to the proposed rule that the results of the IEUBK model-based analysis at relatively low soil-lead concentrations are dependent upon modeling assumptions that are sensitive to local conditions, for example the transport of outdoor soil into a residence. Although the IEUBK model predicts substantial benefits resulting from abatement at higher soil-lead levels, the absence of site-specific information at lower soil-lead levels increases the uncertainty in the public health protection that should be expected. Consequently, EPA does not believe that, as a uniform national soil-lead standard, a value as low as 400 ppm yard-wide represents a reasonable public policy choice. Also, much of the benefit that the IEUBK model-based cost-benefit analysis predicts is very sensitive to certain of the data and assumptions used therein. For example, a significant proportion of these benefits are associated with changes in dust concentration, which are affected by both the HUD National Survey data and EPA's assumptions about post-intervention dust concentrations.

Second, EPA's Empirical-based model cost-benefit analysis has an even greater difference with the IEUBK cost-benefit results with respect to the risk reduction achievable at soil-lead concentrations as low as 400 ppm yard wide. Had the Empirical-based analysis yielded results more similar to the results of the IEUBK model-based approach, EPA would have greater confidence that significant risk reduction is achievable at soil-lead concentrations between 400 ppm and 1,200 ppm as yard-wide standards for most properties.

In addition, EPA considered that, at lower levels, interim controls would be of greater help in reducing risks than at higher levels. While EPA lacks published studies to estimate the effectiveness of these controls, it seems reasonable that interim controls can interfere with exposure pathways and reduce risk. Flexibility to use these measures may aid in taking cost-effective measures where appropriate. EPA, however, was not able at the time of the proposal, and still is not able, to quantify the benefits of interim controls.

The Agency notes that HUD, provided data on interior dust lead measurements at homes where soil interim controls had been instituted. These data included average costs of some interim control strategies and dust measurements approximately 2 years after the controls were implemented. While these data were not used in the risk analyses that support this rule, they were examined in sensitivity analyses that are contained in the Economic Analysis for today's rule (Ref. 14).

An additional reason that supports not using 400 ppm as the yard-wide soil-lead hazard standard is provided by a number of commenters arguing that 400 ppm should be the hazard standard, but that abatement should not occur until 5,000 and interim controls are more appropriate at 400 ppm. These comments come from a number of advocacy groups and State and local governments who are experienced in dealing with abatement issues. EPA disagrees with these comments, for reasons discussed in more detail later in this preamble, because the Agency has decided to base the hazard standards on the lowest levels at which its technical analysis shows that across-the-board abatement on a national level could be justified. Nevertheless, these comments by persons experienced in dealing with control of lead problems, in effect, provide additional support for the Agency's determination that 400 ppm should not be a yard-wide hazard under EPA's methodology for choosing the hazard standards (i.e., that 400 ppm should not be an across-the-board abatement level).

EPA also fears that by calling 400 ppm yard-wide a hazard, property owners and other decision makers would undertake abatements as the automatic response. A value of 400 ppm is below the level at which EPA believes that across-the-board yard-wide abatement and its associated expenditure of resources are justified and at that level could divert resources from potentially riskier sources of lead exposure--namely deteriorated lead-based paint and dust-lead hazards.

EPA also was concerned that more stringent standards would not meet the priority-setting goals the Agency believes are appropriate for the Title X program. Of particular concern was the fact that the Agency estimates that over 12 million homes would exceed a 400 ppm yard-wide standard. Scarce resources potentially would have to be allocated across more communities and would be diverted away from interventions needed to respond to both deteriorated interior and exterior lead-based paint.

With respect to the not choosing a level of 5,000 ppm as the hazard standard, EPA found that while costs may be lower at that level, the IEUBK model-based approach shows that net benefits also decrease by $ 32 billion when increasing the standard from 2,000 ppm to 5,000 ppm. While the empirical model-based approach shows that net benefits are about the same for both options, the benefits decline by $9 billion when the standard increases from 2,000 ppm to 5,000 ppm. Thus, the absolute benefits at 2,000 ppm are substantially higher.

As discussed in the preamble to the proposed rule, however, the difference between 1,200 ppm and 2,000 ppm as the yard-wide standard was a closer call. While 2,000 ppm was justified by both the IEUBK and the Empirical model based analysis, there still was concern for substantial risk at 1,200 ppm. At 1,200 ppm in soil, the IEUBK model estimates a mean blood lead level in the range of 8 to 11 μg/dL. This range of mean blood-lead concentrations corresponds to a range of approximately 30 to 60% exceeding 10 μg/dL and 2 to 10% exceeding 20 μg/dL. In addition, there is a much smaller difference in homes affected when comparing the 2,000 ppm and 1,200 ppm standards as opposed to comparing 2,000 ppm with 400 ppm. At 1,200 ppm, 4.7 million homes would exceed the standard.

EPA decided to propose 2,000 ppm for several reasons. Readers are referred to the preamble to the proposed rule for details. First, the results of the empirical model-based normative analysis showed that net benefits are positive and near the maximum level at 2,000 ppm. The IEUBK normative model-based analysis showed positive and significantly higher net benefits at concentrations up to 2,000 ppm than for soil-lead concentrations above 2,000 ppm. Because both analyses showed positive net benefits at 2,000 ppm, EPA was confident that this level represented a reasonable public health policy choice.

The second reason EPA gave in the proposal for choosing 2,000 ppm was that, outside of its use in the economics model, the IEUBK model predicts significant risk to children at that soil-lead concentration under virtually all exposure scenarios. At 2,000 ppm in soil, the model estimates a mean blood lead level in the range of 11–16 μg/dL, depending upon the assumed concentration of lead in house dust (100–1,400 ppm in this case). This range corresponds to approximately 55 to 80%

equal to or exceeding 10 μg/dL and 9 to 30% exceeding 20 μg/dL. Although this is greater than empirical data, the Agency believes that this application of the IEUBK model supports the conclusion that a level of 2,000 ppm would result in adverse effects.

The third reason given in the proposed preamble to support the 2,000 ppm soil hazard level was that data from a number of epidemiological studies show that between 40 and 50% of the children living in certain communities with soil-lead concentrations at the 2,000 ppm level have blood-lead concentrations equal to or exceeding 10 μg/dL and that 10% of children have blood-lead concentrations equal to or exceeding 20 μg/dL.

However, there are several limitations associated with the above analysis. First, the results are based on a single media analysis, i.e., the estimated percent of children with elevated blood-lead concentration considered only the level of lead in soil and did not control for the contribution of lead from other media to blood lead level. Second, studies were conducted over a period of time between 1979 and 1996 and the study duration varied from a couple of months to several years. Third, the studies were conducted in different geographical regions. Some of the studies were performed in the vicinity of smelters (active or inactive) or in ore processing communities. Fourth, the target populations were different among the studies (i.e., targeting children with 5-20 μg/dL blood-lead concentration, high-risks neighborhoods, homes with a lead-poisoned child, children in a certain age group).

In the proposal, EPA decided not to use as its preferred option the more stringent soil-lead hazard standard. While EPA interpreted the balancing of costs and benefits under IEUBK model-based analysis as showing costs would be at least commensurate with risks at 1,200 ppm, the results of the empirical model-based approach suggested they might not be. In addition, some epidemiological data indicated substantial risks even at 1,200 ppm. Because the Agency's analysis, thus, showed that at the national level costs may not be commensurate with risk reduction at the lower level. EPA decided to propose the higher level because it ''was mindful of the impacts that the costs of soil abatement could have on individual properties and communities.'' (63 FR 30330) This was notwithstanding the fact that some epidemiological data indicated substantial risks even at 1,200 ppm. Ultimately, therefore, the consideration of costs and their impacts was the primary reason why EPA proposed 2,000 ppm as opposed to 1,200 ppm.

At the time of the proposal, the Agency also expected that measures undertaken in response to the proposed soil-lead level of concern in guidance and dust hazard standards would help protect children exposed to soil-lead concentrations at all levels below 2,000 ppm.

EPA received numerous comments on the proposed standard which provided a broad range of perspectives but no clear consensus. Comments that questioned whether the proposed standard would be adequately protective of children did cause the Agency to rethink its approach in reviewing the results of the analysis and the assessment of the available options. While EPA did not choose the options at the extremes, the Agency's principal dilemma as it considered comments on the proposed rule was to consider whether it should retain 2,000 ppm as the soil hazard standard or move to 1,200 ppm. EPA also received many comments that it should establish a separate play area standard. The Agency has resolved these problems, for the final rule, by establishing a 400 ppm standard for children's play areas and an average of 1,200 ppm standard in the remainder of the yard. The following discussion presents EPA's rationale for selecting 400 ppm as a children's play area standard and for selecting 1,200 ppm as the hazard standard for the remainder of the yard and for not choosing 2,000 ppm.

A. Play area hazard standard. As explained above, EPA's proposal was to establish a single hazard standard that would be used for the entire yard. Many comments were received on this approach that were highly critical of the Agency for not treating the play area separately from the rest of the yard. These commenters reasoned that the play area is where children receive a significant proportion of their exposure to soil and that, therefore, the Agency should establish a more stringent standard for play areas. The Agency is persuaded by these comments and has reconsidered its treatment of play areas.

The Agency's initial reluctance to considering a separate standard for play areas was the concern that play areas could not be readily distinguished from the remainder of the yard. Among the comments that urged the Agency to consider a separate standard were comments from local public health agencies stating that risk assessors can readily identify play areas, thus making EPA's primary objection to this approach (feasibility), moot. Given that, in responding to these comments, the Agency, consistent with the interpretation that was stated in its proposal, focused upon the condition and location of lead in soil that would result in adverse health effects. As opposed to assuming equivalent exposure from all areas of the yard, the Agency agrees that it is also appropriate to consider that the extent of exposure and the potential for risk reduction is much greater in play areas. Consequently, because of the high levels of exposure that almost by definition correspond to a ''play area,'' the Agency believes it appropriate to consider 400 ppm to be a soil-lead hazard when that soil is situated in a child's play area.

The Agency's next step was to attempt to estimate how a separate play area standard would affect the risk reduction that would result from various other standards (e.g., 1,200 ppm and 2,000 ppm) in the rest of the yard. The Agency tried various options to partition children's expected exposures from soil in play areas and soil in the rest of the yard. This posed numerous problems, which will be described later in this section, but it did indicate that an approach which focuses primarily upon a child's play area would likely be preferable in terms of protectiveness, risk reduction, and cost-effectiveness.

In its analysis, the Agency considered two options for the degree of exposure: (1) That 50% of exposure is from play area soil and 50% is from soil in the rest of the yard; and (2) that 2/3 of the exposure is from play area soil and 1/3 is from soil in the rest of the yard. The Agency coupled these exposure assumptions with two assumptions regarding the relative size of the play area: (1) That 10% of the yard is the play area (''small yard''); and (2) that 50% of the yard is the play area. These analyses indicated that, in situations where the play area is small, an approach which establishes a more stringent standard for the play area can be more optimal in terms of cost effectiveness (and obviously more protective) than a less stringent standard applied to the yard as a whole.

For example, in the ''small yard'' case where exposure is assumed to be 50% from the play area and 50% from the rest of the yard, the consequences of moving from a yard-wide average standard of 1,200 ppm to standards of 400 ppm for the play area and 1,200 ppm for the rest of the yard are as follows: total costs are increased slightly from $68.9 to $70.4 million while total benefits increase from $159.3 to $174.2 million, using the IEUBK model. This results in an increase in net benefits from $90.4 to $103.8 million. Using the Empirical model, this analysis produces

the same trend, although the results are less dramatic, indicating an increase in net benefits of $1.4 million. The results of these analyses confirm that the establishment of a separate, more stringent standard for play areas can constitute a more targeted, more protective, and more cost-effective approach, especially where play areas are not large.

As noted above, while the Agency believes that these analyses are indicative of the benefits of separate standards for the play area and the rest of the yard, there are a number of technical problems associated with such analyses. First, the amount of direct exposure to soil that children experience in their play areas versus the rest of their yard has not been studied to any significant degree. A further complication is the fact that there is little or no data on the actual, or even relative, sizes of play areas. Additionally, the soil in the rest of the yard can re-contaminate play areas where interventions have previously occurred. For these reasons, the Agency was unable to develop definitive estimates of risk and available risk reduction for separate standards for the play area and the rest of a yard.

The Agency believes that these analyses serve to demonstrate that, to the extent to which children's exposure to soil is greater in a play area and the size of the play area is smaller compared to the rest of a yard, greater risk reduction (and at a lower cost) would be achieved with a separate standard for a play area and a different standard for the rest of the yard (as opposed to applying a single standard to the entire yard). Consequently, the Agency believes that establishment of a more stringent standard for the play area will be more cost-effective as well as more protective of children.

B. Remainder of yard hazard standard. EPA believes that, based on the technical analysis, either an average of 1,200 ppm or 2,000 ppm level could be chosen under the applicable statutory criteria that the conditions of lead-contaminated soil would result in adverse health effects. EPA chose 1,200 ppm for the final rule because it is the most protective level at which EPA has confidence that the risks warrant abatement.

EPA's most basic reason for choosing 1,200 ppm over 2,000 ppm is that the IEUBK model estimates that an individual child would have a 30 to 60% risk of having a blood lead level equaling or exceeding 10 µg/dL, and that some epidemiological data indicated substantial risk at 1,200 ppm. EPA recognizes that this is an overestimate because it was derived without consideration of a play area. EPA recognizes that with separate consideration of a play area, the overall individual risks will likely be lower. It is also important to note that the epidemiological data referred to as indicating substantial risk at 1,200 ppm is the same data, and subject to these same caveats as are discussed in the soil hazard standard section. Also, the Agency notes that abatement at levels above 1,200 ppm have been shown to result in declines in childrens' blood-lead levels. For example, in evaluating the Boston portion of the Urban Soil Lead Abatement Demonstration Project (Ref. 17), the Agency found that:

> ... the abatement of soil in the Boston study resulted in a measurable, statistically significant decline in blood lead concentrations in children, and this decline continued for at least two years. It appears that the following conditions were present, and perhaps necessary for this effect: (a) a notably elevated starting soil lead concentration (e.g., in excess of 1,000 to 2,000 ug/g (ppm)); (a marked reduction of more than 1,100 ug/g in soil lead consequent to soil abatement accompanied by (c) a parallel marked and persisting decrease in house dust lead.

None of these factors, alone, would lead to choosing 1,200 ppm. When combined with the range of uncertainty in either of the cost-benefit analyses, however, the support of the IEUBK cost-benefit analysis, and the nearness to the empirical-based model analysis that would support the 2,000 ppm standard, these factors tip the balance towards the lower of the two levels.

EPA finds national data are not inconsistent with the IEUBK individual risk analysis. EPA estimates, based on the HUD National Survey Data that 4.7 million homes have soil-lead levels that exceed 1,200 ppm. Of these 4.7 million homes, an estimated 830,000 would be occupied by children under the age of 6 (based on the estimate from the 1993 American Housing Survey that 17.6% of homes are occupied by children under the age of 6). According to the IEUBK prediction, elevated blood lead levels due to lead in soil exceeding 1,200 ppm could be found in 30% of these children (based on the lower end of the IEUBK predicted individual range, without consideration of the play area standard), about 250,000 children. Since over 900,000 children, nationwide, have elevated blood-lead levels EPA finds it credible that soil-lead could be a factor in these childrens's blood levels.

EPA decided not to select its proposed choice for the soil-lead hazard standard, 2,000 ppm, for several reasons. First, the Agency's analysis shows that there is substantial and credible risk at soil-lead concentrations below this level. Second, significant risk reduction is possible below this level.

In making its decision, EPA was mindful of the concerns associated with lowering the soil standard from 2,000 ppm to 1,200 ppm. By picking a more stringent hazard standard, EPA increases the estimated number of homes that are potentially affected by 2.2 million. Abatement costs may also divert resources from efforts to control exposure from deteriorated paint and dust which are possibly more significant sources of exposure.

Nevertheless, experience with interim control programs is increasing and certain organizations, particularly public health and housing agencies, believe they have been able to develop effective programs for interim controls which achieve virtually the same degree of risk reduction as do abatement programs, but at much reduced cost. EPA received comments on this issue during the public comment process. EPA wishes to encourage the continuing evaluation of such efforts because resources to deal with hazardous lead levels may be very limited, and strategies which achieve comparable risk reduction, but at much reduced cost, have the potential to protect more children by allocating the limited resources more effectively. Recognizing that a site-specific evaluation may identify unacceptable risks to children, it may be necessary to take a more rigorous approach to mitigate those risks as the lead-levels increase. EPA believes that public and private organizations should evaluate both interim control and abatement strategies in determining the most effective course of action when dealing with dust and soil hazards.

C. De minimis area of bare soil. In the proposal, EPA considered whether the rule should include a minimum (i.e., *de minimis*) area of bare soil as part of the lead hazard criteria. 63 FR 30337-8. The Agency rejected inclusion of a *de minimis* area of bare soil for the hazard standard, but did request comment on two other options. Under one of the other options, EPA would adopt the *de minimis* area from the HUD Guidelines, which instruct risk assessors to sample yards that have at least 9 square feet of bare soil, with no *de minimis* in the play area. HUD's final rule under section 1012/1013 of Title X incorporates this into its interim soil lead hazard standard. That is, a hazard does not exist where there are less than 9 square feet of bare soil outside the play area.

EPA still rejects including a *de minimis* area of bare soil for the hazard standard for the same reasons stated in

the proposal. EPA's reasoning is that the disadvantages of establishing a *de minimis* outweighed the advantages. EPA has no analysis or data that relate the amount of bare soil to risk. EPA also believes that a *de minimis* area of bare soil provides little benefit. First, information provided by an experienced risk assessor suggests that very few properties would be excluded using the *de minimis* in the HUD Guidelines. Second, the incremental cost of including soil testing in a risk assessment is small. Moreover, the *de minimis* used in the HUD Guidelines does not account for differences in yard size. Outside of the play area, 9 square feet may be insignificant in a suburban yard but large for the back yard of an urban row house.

However, EPA highly recommends using the HUD Guidelines for risk assessment (Ref. 5). This would avoid declaring very small amounts of soil to be a hazard in the non-play areas of the yard. This would also help target resources by eliminating the need to evaluate soil or respond to contamination or hazards for properties where there is only a small amount of bare soil.

D. Management of removed soil. EPA is adopting the proposed requirement for management of soil removed during an abatement (63 FR 30343). This requirement prohibits the use of soil removed during abatement as topsoil in another residential property or child-occupied facility. In response to comment, EPA would like to clarify that applicable Federal and State requirements apply to removed soil including testing pursuant to RCRA under the Toxicity Characteristic Leaching Procedure and disposal of soil identified as hazardous waste (Ref. ?). The Agency also advises that care should always be taken to ensure that removed soil does not pose immediate or future risks to human health. For example, it should not be disposed of at an undeveloped site that may later be developed as residential or converted into a playground.

c. *Paint.* This section of the preamble presents EPA's decisions regarding the standards for hazardous lead-based paint. It addresses the deteriorated paint, paint on friction and impact surfaces, and surfaces accessible for chewing or mouthing by young children. This section also discusses relevant amendments to sampling requirements.

i. *Deteriorated paint.* The final regulation adopts the Agency's underlying rationale in the preamble to the proposed rule for setting the hazard standard for deteriorated paint. Specifically, EPA reaffirms its argument in the preamble to the proposed rule (63 FR at 30330–30331) that the available evidence demonstrates a relationship between deteriorated lead-based paint and blood-lead. Due to the continuing lack of data, however, EPA is still unable to definitively select an area threshold below which the lead-based paint would not be a hazard. Further, EPA has received substantial public comments that even very tiny amounts of deteriorated paint can cause harm and should be addressed. As a result, the Agency has reevaluated its rulemaking record and no longer believes it is appropriate to have a threshold level of deteriorated lead-based paint below which a paint-lead hazard does not exist.

Accordingly, EPA has decided to identify as the paint-lead hazard any deteriorated lead-based paint, except in the case of friction surfaces. For friction surfaces, as noted below, a paint-lead hazard may exist if the surface is subject to abrasion and dust lead levels on the nearest horizontal surface underneath the friction surface are equal to or greater than the dust hazard levels.

Furthermore, EPA has decided that it was not appropriate to refer to any area threshold for deteriorated lead-based paint as a *de minimis* threshold. Using this terminology gives the public the perception that the Agency believes risks at lower levels of deterioration are inconsequential and that no action should be taken.

While establishing this paint-lead hazard standard would alert the public to the fact that all deteriorated paint needs to be addressed, EPA acknowledges that paint stabilization or interim controls (activities less than abatement) would often be appropriate to address paint, particularly at lower levels of deterioration or where the deterioration is minor, such as less than: Two square feet of deteriorated lead-based paint per room; 20 square feet of deteriorated exterior lead-based paint; or 10% or less of deteriorated paint on the total surface area of an interior or exterior type of component with small surface area. EPA, further, emphasizes that applicable HUD and EPA regulations do have area threshold exemptions for various work practice standards, clearance, and certification requirements.

A. Comparison of proposed and final rules. EPA proposed to adopt as the paint hazard threshold levels those levels identified in the 1995 HUD Guidelines that defined paint in poor condition. These levels were ''component based.'' That is, there were more than 2 square feet of deteriorated lead-based paint on any large interior architectural component (e.g., floors, walls, ceilings, doors, etc.), more than ten square feet of deteriorated lead-based paint on any large exterior architectural component (e.g., siding), or deteriorated lead-based paint on more than 10% of the surface area of any small architectural component (such as window sills and baseboards). Under HUD's Guidelines no action was required for paint with lesser amounts of deterioration.

The Agency proposed using the criteria in the HUD Guidelines because they were becoming the de facto industry standard that was being considered for incorporation into model housing and building codes and by State officials for adoption as State standards. In addition, EPA decided that relatively small thresholds are needed to be protective, because the area of deterioration has the potential to increase over time and because the presence of even small amounts of deterioration can present a significant risk to children who exhibit pica for paint. EPA also noted that with an area threshold level in place, millions of homes would not be identified as having hazardous paint and that this would reduce the number of paint abatements while still providing protection to the populations of concern. Nevertheless, the preamble to the proposal emphasized that while areas of deteriorated paint that fall below the threshold would not be considered a hazard, property owners should try to keep paint intact, especially paint known to be lead-based, because of the risk to some children.

EPA received numerous comments on the issue of the area threshold. Comments varied from those that argued that all lead-based paint, regardless of condition, should be a hazard to those that argued the Agency should have no separate paint standard but should rely on the dust and soil standards. Comments in between recommended such standards as all deteriorated paint should be a hazard, or that the area thresholds should be lower or more clearly explained. As a result of considering the comments and all other information available in the rulemaking record, EPA is issuing a final rule that generally provides that any deteriorated lead-based paint would be identified as a hazard. Below, EPA explains its final decision. Detailed responses to all significant comments are found in the RTC document.

While there were no comments that could directly quantify the relationship between deteriorated paint and blood lead levels, two comments attempted a

very rough quantification that EPA can use for limited support for its determination that any deteriorated lead-based paint is a paint-lead hazard. One comment cited an analysis by the Consumer Product Safety Commission (CPSC) suggesting that very small areas of deteriorated lead-based paint could present hazard to young children. According to this analysis, chronic ingestion of lead from paint and other consumer products should not exceed 15 ug/day to prevent a young child from having a blood lead levels that exceeds 10 µg/dL. Assuming a 30% absorption rate and and paint with 0.5% lead by weight, this analysis estimates that a child would have to ingest as little as 6 square inches of paint over a month to have an elevated blood lead level. Another comment submitted a theoretical calculation that the proposed standard for the dust lead hazard of 50 µg/ft^2 would be exceeded if only one square centimeter of lead-based paint with a concentration of 4 mg/cm^2 were ground into dust and evenly distributed in an eight by ten foot room. Other commenters presented anecdotal evidence that children have been lead-poisoned as a result of exposure to very small quantities of lead-based paint.

In addition, EPA has also considered the fact that HUD's standards, upon which EPA relied as a consensus standard, have changed with the issuance of HUD's final regulations under sections 1012/1013 of Title X. EPA believes it is appropriate to conform its final paint-lead hazard definition to HUD's regulations. It is EPA's determination that HUD is the government agency with the most experience in dealing with residential paint and the Agency has chosen to rely on HUD's judgment in these matters as to amounts of deteriorated paint that would result in adverse health effects. Industry standards tend to follow the leadership of HUD guidelines and regulations. EPA's consideration of the issues involving the uncertainty of choosing a paint hazard area threshold under the statutory standard for determining what constitutes a hazard, as well as a discussion of the history of the HUD standard for hazardous paint and EPA's evaluation of HUD's regulations follow.

B. Uncertainty analysis. Any deteriorated paint could conceivably cause adverse health effects, as noted by several comments. Furthermore, EPA would want people to know that any deteriorated paint needs to be dealt with. Very small amounts of lead-contaminated paint could be a cause for concern. Even a few paint chips could provide a very concentrated dose to a child that may ingest them. They may prove to be an attractive nuisance (particularly if they are brightly colored) that might encourage a child to ingest them. Any deteriorated surface could rapidly expand, particularly if a child should decide to pick at it. Because of this concern any deteriorated paint should be carefully monitored and stabilized.

The Agency cautions, however, that it does not believe full scale abatement, with all attendant regulations, would be appropriate for all deteriorated lead-based paint, particularly at the lesser areas of deterioration (i.e., less than: 2 square feet of deteriorated lead-based paint per room; 20 square feet of deteriorated exterior lead-based paint; or 10% or less of deteriorated paint on the total surface area of an interior or exterior type of component with small surface area).

Abatement in cases where there are very small amounts of deteriorated paint would make no sense in view of the fact that approximately 60 million residences have some lead-based paint and approximately 13.5 million have some deterioration. The National Survey of Lead and Allergens results will be released in the near future with a different estimate from that on which these numbers were based (Ref. ?). Recommending abatement for all hazards when relatively few children seem to be affected when compared to the total amount of homes with deteriorated paint could result in the cleanup of millions of homes that would result in little to no reduction in risk. Therefore, EPA believes that minimal degradation does not warrant abatement.

Nevertheless, the Agency leans towards being more protective in the face of uncertainties and has decided to have a standard at which any amounts of deteriorated paint would be considered a lead-based paint hazard. The more cracked or deteriorated paint that exists in a residence, the more likely it would be that amount of degraded paint would increase. The greater the deterioration, the more likely the increase in lead in dust. The paint-lead hazard levels would enable people to take protective action before excessive exposure to dust would occur. Since people are not likely to constantly monitor for dust levels, providing a standard that would focus on paint deterioration is an added level of protection. In addition, the more cracking and deteriorated paint that exists, the more likely the lead would be available for potential exposures through ingestion via dust or direct ingestion of paint chips.

In addition, EPA has decided to use the HUD interim standard for the paint-lead hazard (Ref. 5). This is because, in addition to the reasons stated above for having no threshold area, , the HUD standard is a level that people responsible for addressing the paint-lead hazards are either familiar with now or will have to become familiar with and, in the absence of any other definitive level, to choose, it makes sense to use the same standard as a sister agency for ease of identification and compliance. Of course, EPA will reconsider its decision should any information become available to allow choosing a more definitive level.

C. HUD's standard. EPA concurs with HUD's reasoning for setting its interim paint-lead hazards, as discussed in this section. HUD's reasoning for eliminating a level below which no action is required is explained in the preamble to HUD's final 1012/1013 rule. HUD stated that it was convinced by various comments from the public that there should not be an area threshold of deteriorated paint below which no action is required. These comments were: (1) That the *de minimis* exception (as it was referred to at the time) is arbitrary and not supported by science; (2) that the levels are too large, potentially allowing a total of over ten square feet of defective paint per room (counting four walls plus a ceiling plus small components); (3) that some owners or inspectors may use the area threshold as an excuse for overlooking hazardous conditions; and (4) that it is likely to shift the attention of workers from the importance of practicing lead hazard control and maintaining painted surfaces in a lead-safe manner to measuring the size of defective paint surfaces in order to document that surfaces fall above or below the *de minimis* level. (See 64 FR 50156.) In addition, HUD received comments that persons dealing with the threshold levels found it difficult to understand and put in practice. These comments indicated that people would spend too much time measuring the exact areas of deteriorated paint instead of focusing on making housing lead safe. (See 64 FR 50198.)

Based on these comments, HUD's final rule eliminates any provision that provides no action is needed with regard to deteriorated paint. HUD concluded this based on experience in its tenant-based assistance programs (where the area threshold provision was made effective in 1995) that indicated that the area threshold was a cause of confusion. (See 64 FR 50198.) As a result, HUD's final rule provides that all deteriorated lead-based paint (either

known or presumed to be lead-based paint) must be addressed. According to HUD, this would simplify the rule's implementation considerably.

Even though, under HUD's regulation all deteriorated paint must be addressed--through use of paint stabilization or interim controls, HUD nevertheless acknowledges that something less than abatement and, consequently, fully certified personnel, would be needed to address paint at lower levels of deterioration. HUD, thus, retained an area threshold exemption for required work practice and clearance standards. The levels of deterioration in this standard are the same as provided in EPA's TSCA section 402 work practice regulations--2 square feet of deteriorated lead-based paint per room, 20 square feet of paint on the exterior building, or 10% of the total surface area on an interior or exterior type of component with a small surface area. EPA's work practice standards were promulgated on August 26, 1996, 61 FR 45778. These standards have become the industry standard, having been in place since then and having been acknowledged as enforceable standards followed by the public. Thus, under HUD's regulations, activities that disturb painted surfaces of lesser deterioration do not have to use certified workers, work practices required under regulation, or work site clearance. (See 64 FR at 50149, 50156, 50166, 50184, 50185, and 50198.)

HUD had also submitted comments on this proposed 403 rule approximately 1 year before its 1012/1013 rule was issued. These comments were consistent with HUD's eventual final 1012/1013 rule in the sense that they explained that HUD has found it is more practical to require deteriorated lead-based paint of any size surface area to be addressed. HUD commented that use of an area threshold criterion for determining whether any control is necessary has the effect of having inspectors or risk assessors making efforts to measure surface areas instead of focusing on control of deteriorated paint. Further, it had been HUD's experience that some lead-based paint hazards have not been repaired because of confusion on whether or not enough of the paint had deteriorated to warrant attention.

HUD recommended that EPA should eliminate the area threshold for eliminating any need to control deteriorated paint. However, HUD then stated, ''All deteriorated paint of any size should be considered a hazard and should be repaired; however, containment, clearance, and safe work practices need not be required for hazards'' below the area threshold.

D. EPA's decision. For the reasons discussed above, EPA identifies as a paint-lead hazard any deteriorated lead-based paint, for surfaces other than friction surfaces, as noted below. However, EPA notes a caution that there is a level above which serious restrictions should be placed on worker certification and work practice standards and below which such restrictions are not needed. HUD and EPA also agree that any deteriorated paint needs to be dealt with.

Additionally, to attain consistency with the requirements of the 1012/1013 rule in the sense that action less than abatement should be taken with respect to levels below the hazard threshold, EPA is modifying the work practice standards found at 40 CFR 745.227 to require risk assessors to test all deteriorated paint on surfaces with a distinct painting history. This requirement would provide owners and other decision makers with information that would help these individuals take appropriate action (e.g., stabilize small amounts of deteriorated paint, increase monitoring of the property and resident children). Currently, the work practice standards require risk assessors to test paint only where deterioration exceeds the area thresholds. This sampling requirement, as amended, also applies to accessible surfaces. The existing sampling requirements do not separately address paint testing on these surfaces. The sampling requirements for friction and impact surfaces are discussed below.

ii. *Friction and impact surfaces.* In the final rule, a paint-lead hazard exists on a friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface underneath the friction surface are equal to or greater than the dust hazard standard for that surface. A paint-lead hazard exists on an impact surface when there is any damaged or otherwise deteriorated paint that is cause by impact from a related building component such as a door knob that knocks into a wall or a door than knocks against its door frame.

EPA did not include a preferred option for friction/impact surfaces in the proposed regulation, but instead asked for comment on several options (63 FR at 30332–30333). These options included: Any lead-based paint on a friction/impact surface, abraded paint on a friction/impact surface, or no separate standard. In the latter case, the deterioration of paint on friction/impact surfaces would be counted along with the deterioration of all paint to determine hazardous paint, or the dust-lead hazard standard could be relied upon.

The final paint-lead hazards for friction and impact surfaces are within the range of options discussed for the proposal. EPA decided to include a reference to abrasion as a condition of hazard on the friction surfaces because abrasion indicates that the rubbing or impact of the surfaces is likely to generate lead-containing dust. To this condition the Agency added the presence of dust at the dust-lead hazard level because the combination of deterioration with rubbing or impact is likely to generate lead-contaminated dust. In light of the limited data available to EPA, the Agency issued a standard based on a reasoned and common sense approach that identifies conditions likely to contribute lead to dust and the existence of dust at the hazard level. Even with the condition of deterioration added, this option falls within the bounds of the alternatives presented in the proposal. It is more stringent than the alternative based on abrasion alone but less stringent than the option that would identify any lead-based paint on a friction and impact surface as a hazard.

In promulgating the friction surface paint-lead hazard standard, EPA has considered those comments that urged the Agency not to establish a separate standard for friction and impact surfaces, but instead to focus on dust. On friction surfaces, the absence of either a component that is not subject to abrasion or dust-lead at the hazard level would eliminate the component as a paint-lead hazard. This is because a positive dust test (i.e., presence of a hazard) suggests that a friction surface is a source of lead contamination.

EPA also determined that identifying as a hazard lead-based paint on friction and impact surfaces regardless of the paint's condition is inappropriate. The Agency does not believe that intact paint can generate significant amounts of lead-containing dust. Commenters who favored Option 1 failed to provide evidence supporting the contention that these surfaces contribute to lead-containing dust regardless of the paint's condition. The strongest argument presented by a proponent of Option 1 stated that the hazard designation would lead to the testing of these surfaces for the presence of lead-based paint. Property owners and occupants would then, at a minimum, be encouraged to monitor the condition of the paint and keep it intact. Monitoring of paint condition, however, does not require knowledge that the paint is lead-based. EPA believes that owners/

managers/occupants of target housing should monitor the condition of any paint on friction and impact surfaces. If the paint deteriorates or becomes abraded at any point and young children occupy the residence, the paint should be tested to determine if the paint is lead-based and if a hazard exists. Furthermore, if the component has any abraded or deteriorated paint, it would have to be tested as part of a risk assessment.

The final regulatory decision has also led EPA to amend the sampling requirements for lead-based paint under the work practice standards for risk assessments at 40 CFR 745.227. This amendment will require risk assessors to sample any visibly abraded or deteriorated paint on friction and impact surfaces as part of a risk assessment.

iii. *Accessible (chewable) surfaces.* The final rule at § 745.65(a) uses the term ''chewable'' surface to refer to the statutory term ''accessible'' surface. A paint-lead hazard exists on any chewable lead-based paint surface on which there is evidence of teeth marks. EPA did not include a preferred option for accessible/chewable surfaces in the proposed regulation, but instead asked for comment on several options (63 FR 30333). These options included: Any lead-based paint on a interior window sill up to 5 feet off the floor; and no separate standard.

EPA decided to include a standard for chewable surfaces in the final rule, which is more stringent than no separate option and less stringent than any lead-based paint on interior window sills, for the following reasons. EPA has added evidence of chewing as a factor for determining whether a paint-lead hazard exists and has eliminated any requirement that the chewable surface must be up to 5 feet from the floor. The data available to the Agency indicate that chewing on protruding components is extremely rare, it nevertheless presents a cause for concern. Accordingly, evidence that chewing occurs would enable the public to focus attention on those areas where the risk is real. Further, by adding this evidence of chewing requirement, there would be no reason to retain any height requirement for the chewable surface. If there is evidence of chewing on a lead-based paint surface, there need be no other factor to consider.

The option that would identify lead-based paint on interior window sills regardless of paint condition as a hazard is not likely to protect any significantly larger amount of children than would be protected by the requirement to have evidence of chewing. On the other hand, such a stringent requirement could lead to action in millions of other properties where children do not exhibit this behavior, diverting resources from more significant sources of exposure such as deteriorated paint and lead-containing dust.

Most proponents of this option or options to include a broader range of surfaces failed to provide a compelling basis to EPA for selecting this or broader options because they did not provide supporting data (and most did not provide analysis). One State health department suggested that this option would lead to paint testing of these surfaces. Property owners and occupants would then, at a minimum, be encouraged to monitor conditions. EPA recognizes that it would be useful to know if chewable surfaces are covered with lead-based paint so that these surfaces and the chewing behavior of resident children can be monitored by owners and occupants. Chewing behavior by young children, however, can and should be monitored in the absence of this knowledge. This approach would avoid widespread testing of intact paint, which is costly and may require damaging the paint in situations where an x-ray flourescence (XRF) instrument cannot be used.

Several other commenters noted the data that EPA presented relates to chewing, not mouthing of surfaces. Although mouthing may be more frequent than chewing, exposure is less likely to result from mouthing of intact surfaces. If the paint on interior window sills is intact, it would likely have been repainted since lead-based paint was banned for residential use over 20 years ago. Consequently, a child who mouths intact paint would likely come in direct contact only with paint that is not lead-based and meets the Consumer Product Safety Commission standard for new residential paint (i.e., 0.06% by weight). It is important to emphasize that EPA does not intend to imply that mouthing of intact painted surfaces is risk-free behavior. Mouthing of intact paint may result in exposure to low levels of lead and other chemicals and, therefore, should be avoided.

The Agency wishes to note that it is very concerned about the potential exposure for the relatively few children who do chew on intact lead-based paint on such surfaces. The Agency has concluded that the best way to protect these children who do chew on such surfaces is through guidance that strongly recommends immediate action when such behavior is observed. A range of responses is available to property owners and other decision makers, such as plastic or metal coverings.

iv. *Requirements for interpreting paint sampling.* EPA is adopting the proposed requirements for interpreting paint sampling results (63 FR 30339) except for one clarification that is being made in response to a comment from HUD. The Department stated that language regarding the assumption risk assessors should make about paint on surfaces that have not been tested was unclear. The proposed requirement stated that the risk assessor is to ''assume all like surfaces that have a similar painting history contain lead-based paint if the tested component has lead-based paint.'' HUD asserts that the term ''like surface'' is ambiguous as to whether it refers to building components in the same room equivalent or anywhere in the building. Chapter 7 of the HUD Guidelines indicates that this extrapolation can be made only to components in the same room equivalent, with extrapolation to untested room equivalents appropriate only in restricted circumstances. HUD, therefore, recommends that the method be amended to read ''assume all like surfaces in the same room equivalent that have a similar painting history . . .'' EPA agrees with HUD that the term ''like surfaces'' is ambiguous and has changed the language to read ''like surfaces in the same room equivalent.''

The requirements for interpreting the results of paint testing apply to friction and impact surfaces, chewable surfaces, and other surfaces with deteriorated paint. EPA is also adopting the provision that allows risk assessors to use composite paint sampling. The Agency wishes to restate the point made in the proposal (63 FR 30339), however, that composite sampling for paint can be used to rule out the presence of lead based paint but cannot be used to identify the specific sample (and therefore component) that is lead-based. Therefore, a risk assessor should only use composite testing if he or she is reasonably confident that lead-based paint is not present on the surfaces sampled.

4. *Certified risk assessor requirement.* In the proposed rule, EPA included a requirement that lead-based paint hazards be identified by certified risk assessors following the risk assessment work practice standards and that ex situ sample analysis be performed by recognized laboratories. The Agency argued that this approach would ensure the reliability of sampling results and provide flexibility for future changes in hazard evaluation technology.

This issue received substantial public comment and raised concerns which

have led the Agency to reconsider promulgation of this requirement. Many commenters believed that such a requirement would inhibit the ability of communities and individuals to identify lead-based hazards, and to deliver services or pursue response actions to protect children when an obvious hazard is present, due to the cost of full risk assessments and the lack of availability of risk assessors. Other commenters questioned the Agency's authority to mandate such a restriction. Some commenters believed that certification was appropriate and necessary to ensure the quality and reliability of hazard determinations, but questioned the need for full risk assessments or for such lead-based paint activities to be restricted to risk assessors. Some commenters also suggested that a screening procedure be allowed in lieu of a full risk assessment.

In reconsidering its proposed requirement, the agency agrees with the comments that current shortages and surpluses both in availability of risk assessors, and potentially high costs for full risk assessments could, in certain localities, impede response actions for at-risk children. It also recognizes that for certain hazard determinations, such as the visual determination of deteriorated paint, or analysis of dust levels, a full risk assessment may not be appropriate and may waste scarce resources available for hazard control or abatement.

The Agency also recognizes that a certified risk assessor may not be necessary for the simple visual determination of deteriorated paint, and that such more elementary evaluations of hazards at a property could potentially be performed by individuals with less training and experience than a certified risk assessor, and that such limited activities may not in themselves require certification, but may be performed effectively and reliably when the person performing those activities does so under the supervision of a certified risk assessor or other certified lead professional. In addition, the Agency did not intend to require that certified risk assessors be required to perform clearance sampling following abatements. For these reasons, the Agency believes it prudent to deal with these general issues in subsequent rulemakings and regulatory interpretations which will further address work practices and /certification requirements for both.

While the Agency believes that these issues are best addressed in the overall framework of the section 402 work practices and certification standards, it is nevertheless concerned that those uncertified individuals who may seek to determine hazards may not always produce results of the same quality and reliability as those obtained by a certified risk assessor, and that the use of uncertified personnel to determine the presence or absence of lead-based paint hazards should be considered with caution.

Sampling of dust and soil to determine lead-based paint hazards is not a trivial procedure. The procedures which must be followed by risk assessors in determining the nature and extent of lead-based paint hazards at a property are stated at 40 CFR 745.227. If uncertified individuals are used to determine hazards, it is critical that they have the appropriate training, and follow appropriate procedures for sampling, custody of samples, and analysis of samples to obtain defensible results. If uncertified persons lack the training and experience to determine lead-based paint hazards properly, their findings may result in detrimental consequences to the health of children and create false liabilities for property owners. A false negative result--the failure to determine the presence of a hazard when one actually exists, will fail to protect children from real hazards. A false positive result--the determination of a hazard when none is present--may cause an owner to spend additional resources to hire a certified risk assessor.

IV. Overview of Significant Public Comments and EPA's Responses

In response to the proposed rule, EPA received over 500 comments representing the general public, national and local environmental groups, national and local lead-poisoning prevention advocacy groups, the lead mining and manufacturing industry, State and local governments, other Federal Agencies, community-based organizations, and Federal Advisory Committees, among others. These comments address numerous issues, including EPA's interpretation of the statutory requirements, the policy basis for the standards, the Agency's technical analysis, and the Agency's decisions regarding the standards and other regulatory requirements. As noted previously, the RTC document contains EPA's detailed characterizations and responses to all significant public comments.

This section of the preamble presents in summary form, the characterizations and responses to the comments on the issues that EPA believes are of greatest interest to the public. These comments, specifically, are as follows: (1) It is not appropriate under the statutory requirements of Title X, or from a policy perspective, to consider costs in the development of the hazard standards; (2) standards would fail to protect children in inner-city neighborhoods who are at greatest risk; (3) the dust hazard standard should be significantly lower; and (4) EPA should provide a better explanation of the differences between the TSCA section 403 hazard standards for soil and the Superfund approach for addressing lead in soil.

A. Consideration of Costs in Developing Dust and Soil Hazard Standards

As discussed extensively in the preamble to the proposed rule, this preamble and the RTC document, EPA chose to base its dust and soil hazard standards on consideration of the potential for risk reduction of actions that may be taken (considering uncertainties in the data and scientific evidence describing the risks) and whether such risk reductions are commensurate with the costs of those actions. This is commonly referred to as cost-benefit balancing. Further, the Agency has decided to base the hazard standards on the levels at which, on a national level, risks justify abatement in order to comply with the statutory standard that the hazard levels are those that ''would result'' in adverse health effects. EPA has noted, however, in various places throughout this preamble, that temporary measures and interim controls can be appropriate in many situations. The analysis of abatement, as noted further below, is EPA's analytical model. The Agency may not require any particular action to be taken.

A number of comments from some advocacy groups and some government organizations expressed general disagreement with this approach from both a legal and policy standpoint. Other comments provided detailed arguments both for and against this approach. EPA responds in the RTC document to the more detailed arguments raised by these comments. However, the Agency believes it is appropriate to discuss the issue more generally in this preamble to clear up important issues and to allay apparent fears of some members of the public.

Comments criticizing EPA's use of cost-benefit balancing generally argued that it is inappropriate to make decisions regarding the selection of hazard standards based on cost or other risk management considerations. Serious concern was expressed that EPA modified health-based protective standards by cost, or feasibility, considerations and that scientific decisions about a health based standard

cannot be modified by such considerations. These comments argued that EPA should have made decisions by tying hazard standards to a target blood lead level. Costs and other risk management factors should only be considered by persons implementing the standards.

EPA believes it is necessary to explain how cost-benefit balancing was used in this rulemaking. First, the decision to use a cost-benefit balancing approach is within the Agency's statutory authority. Title X and TSCA Title IV neither require nor preclude the consideration of costs in setting the standards. EPA's interpretation of the statute, however, shows that an approach that uses cost-benefit balancing is consistent with the statutory language and legislative history, as described more fully in the proposal (63 FR at 30312-30314), earlier in this preamble and the RTC document.

A cost-benefit balancing framework provides EPA with an approach to factor uncertainty in scientific data into the decisionmaking and to set standards where there are no distinct boundaries. For this action, EPA's dilemma is to choose as a hazard that level of lead above which the Agency is reasonably confident that adverse effects would result. Below that level there may still be adverse effects, but the weight of scientific evidence indicating adverse effects is not as great. This formulation, of course, is an over simplification by necessity. The Agency is tasked with line drawing by Congress in a circumstance where there are no clear lines. At the simplest level, no one can say that 1,201 ppm of lead in soil is worthy of abatement and 1,199 ppm is not. As a result, consistent with the applicable statute, EPA used a balancing approach to pick the cutoff level above which a regulatory hazard exists.

EPA's approach first, and foremost, considers the weight of evidence as to whether dust or soil lead will actually result in adverse effects. The surrogate for adverse effects is a consideration of blood lead levels and the potential effects elevated blood-lead levels can have on intelligence and lifetime earnings. Reduction in blood lead levels and, presumably, increased lifetime earnings are then related to reduction in environmental levels. No one would dispute that the higher the environmental lead levels are in any particular medium (e.g., soil or dust), the greater the likelihood of increased blood-lead due to exposure from that medium. At low environmental lead levels, there is less confidence that any specific medium is responsible for blood-lead level increases. EPA's problem is drawing the line at which concern for exposure to lead from paint, dust, and soil diminishes that is, those levels below which EPA will decide a regulatory hazard does not exist.

EPA, using the best scientific evidence it had, did the line drawing by assigning a monetary value to the health effects that will be prevented (''benefits'') and evaluating whether elimination (abatement) of the lead hazard that causes these effects is commensurate with the societal resources (determined by the costs of abatement) that would be expended by doing the abatement. This gives EPA a way to evaluate the certainty of the scientific evidence and develop the confidence it needs to determine that the levels it has chosen would result in adverse effects. Essentially, in this area of scientific uncertainty about risk, EPA is more willing to say that a regulatory hazard exists if it can find that costs of abatement are expected to be reasonable. Costs, of course, are given far less weight (or maybe no weight at all) in circumstances in which adverse effects are a certainty. Certainty simply does not exist at the lower lead levels with which the Agency is dealing in this rule.

Two salient points need to be reiterated here on how a cost-balancing analysis was used in this rulemaking. In the first place, for this rule, cost-benefit balancing is a useful method for decision making within the range of uncertainty in the Agency's analyses. In any event, use of the analysis only helps define the boundaries of the inquiry and is not a sole basis for any decision. Once EPA decided the range of options, the Agency chose the levels within those ranges. Second, EPA used the normative cost-benefit analysis only to compare options with the understanding that the relative balance of costs and benefits estimated should be reflective of the relative balance of actual costs and benefits. Thus, decision makers still needed to exercise judgement. There is no ''black box'' into which numbers are entered and a decision comes out.

The comments that object to EPA's approach for hazard determination for dust and soil offer as an alternative determination of hazards by reference only to environmental levels that are associated, through modeling, with a percentage of children exceeding various blood lead levels. For example, a hazard standard could be that level at which models show no more than 5% of children would exceed 10 μg/dL of blood lead. This type of standard would be based solely on the toxicity of lead (at a particular blood level) and the potential exposure. While EPA did use this method for picking the initial candidate hazard levels, the Agency declined to use this method for choosing hazards.

The reasonableness of EPA's approach is supported to a large extent by the fact that the Agency received several comments recommending particular blood levels and percentages but no comment provided EPA with any kind of rational basis for choosing the standard based on those levels and percentages. Most of these comments argued for having no more than 5% of children above 10 μg/dL. However, they provided no rationale for saying why this would meet the ''would result'' standard for determining lead-based paint hazards (i.e., why shouldn't we have zero children above 10 μg/dL, or why 10 μg/dL is the proper number for the hazard determination and not a higher or lower number).

EPA's view of the cost-benefit approach points out another misconception in the comments about cost-benefit analysis. This misconception is that EPA's approach is not health-based, but instead modifies a protective standard based on cost considerations. Commenters also seem to believe that the Agency is using cost considerations to leave children unprotected. This is not the case. Instead, as discussed above, EPA evaluated different options within the range of scientific uncertainty provided by the two models used in the Agency's analyses. While it is true that as levels get higher, the certainty regarding the probability of harm increases, this does not mean that lower levels should be discounted or never addressed. It may mean, however, that as you go lower, the levels are less likely to meet the goal of this rule to set levels at which all abatements are specified to be conducted in a specific way. For purposes of setting such a national standard, EPA believes that it is reasonable to choose a level within the range at which there is greater certainty regarding the probability of harm, being always mindful of the need to advise the public that lower levels are not risk-free and may in individual cases present significant risks.

Given the range of uncertainty shown in its analyses for this rule, EPA is choosing an option that the Agency believes provides protection, and at which there is a higher level of certainty that in all cases abatement is likely to reduce risks significantly. EPA has set its dust and soil hazard standards at the lowest levels at which it believes across-the-board abatement and its associated expenditure of resources is justified. Evaluation of resource allocation, of which costs are a measure, is a method

that was used in this rule as a tool to make decisions within a set range of uncertainty.

Finally, EPA's hazard standards should not be considered in isolation, but must be considered along with the Agency's tiered approach for paint and soil. Under this approach, the Agency recognizes that risks could exist below the hazard standard and recommends that organizations and individuals may want to consider taking some action, informed by knowledge of local circumstances, at levels below the hazard levels.

B. Standards Do Not Protect Children at Greatest Risk

Groups representing environmental justice and children's health protection interests argued that the standards do not protect children at greatest risk. Some argued that the 1 to 5% probability level for exceeding 10 μg/dL (EPA's basis for choosing the initial candidate hazard levels in the final rule and the Agency's basis for evaluating lead-contaminated dust and soil in the proposed rule) would result in no improvement because the percentage of children with elevated blood lead levels is already below 5%. Therefore, the populations with the highest blood lead levels would not benefit from the standards.

EPA strongly disagrees with this assertion and, in fact, has concluded that the exact opposite is true. The argument that the 1 to 5% probability criteria would result in no improvement for children at risk reflects confusion with respect to the national blood-lead data and risk to individual children. The national blood-lead data is composed of millions of children exposed to a broad variety of environmental-lead conditions. As such, it actually consists of a broad range of individual risks ranging from near zero to levels above 50% for children exposed to the very worst conditions. The average population risk is just below 5%. Children in at-risk communities tend to have the higher individual risk, as borne out by the higher prevalence of elevated blood lead levels in these communities (e.g., > 20% for African American children living in pre-1950 housing).

In fact, the hazard standards identify a higher percentage of African-American children than any other group. Moreover, instead of offering more protection to children in at-risk communities, more stringent standards may actually afford less protection to these children by diluting the resources available to address hazards in these communities.

C. Dust-Lead Hazard Standard Should be Significantly Lower

Several comments argued that the dust-lead hazard should be significantly lower, in the 5 to 10 μg/ft^2 range. They claimed that a hazard should be found because more than 5% of children would have blood lead levels above 10 μg/dL. This recommendation is based on several analyses including an independent analysis of the Rochester Lead-in-Dust Study and the so-called HUD pooled analysis. According to these commenters, these analyses show that significant risk exists where floor dust-lead levels are below 10 μg/ft^2.

EPA agrees that significant risks should be addressed but disagrees with the approach of these commenters. First, as noted above, these comments provided no rational basis for deciding that a regulatory hazard exists based solely on environmental levels associated with particular blood lead levels. Nevertheless, EPA concludes after review of these comments and analyses that the results showing more than 5% of children exceed 10 μg/dL at the low environmental levels were achieved by focusing almost exclusively on the contribution of dust-lead to exposure and not adequately accounting for the contribution of soil and deteriorated lead-based paint to exposure. When exposure to these other sources is adequately accounted for, as EPA believes was done in its analysis, significant risk attributable to dust-lead is not found until dust-lead levels on floors reach 40 μg/ft^2.

The data also indicate that to make predictions of risk based exclusively on dust-lead measurements would be an inefficient and imprudent approach. An examination of the Rochester data reveals that in practically every case where there was a child with an elevated blood lead level and floor dust lower than 40 μg/ft^2, soil-lead levels were elevated and/or deteriorated lead-based paint was present. Moreover, in most houses with dust-lead levels below 40 μg/ft^2, children did not have elevated blood lead levels because other significant sources of exposure were not present.

EPA believes that the above-mentioned empirical data supports its view that it is more technically correct to assess and control exposure in all three media, as opposed to taking an approach that focuses exclusively on dust. Given the uncertainty that exists with respect to the contribution to exposure presented by each medium individually, the Agency believes that it is prudent to control exposure from the combination of paint, dust, and soil together rather than individually. Also, control of all three media also prevents recontamination of one medium by another, making control efforts more effective.

D. Relationship of Soil Hazard Standard to Superfund Soil Cleanup Standards

Several commenters expressed concern about the difference between the TSCA approach for addressing lead in soil in pre-1978 residential property and the approach under programs administered by the Office of Solid Waste and Emergency Response (OSWER) specifically, Superfund sites and RCRA Corrective Action Facilities. Responses to comments on the details of the differences in the programs are addressed in the RTC document. In this section, however, EPA responds generally to issues raised on the relationship between the programs administered by OSWER and TSCA. In general, comments identified concerns that differences in the two programs could cause confusion and that persons responsible for cleanup under the OSWER programs could use the TSCA standard to avoid taking response actions to achieve protection.

As a preliminary matter, EPA emphasizes that at lead-contaminated residential sites both TSCA and the OSWER programs seek to protect the health of the most susceptible population (children under 6 years of age) and to promote a program that assesses and addresses risk. The approaches taken by the various programs share many important aspects, but also differ in some respects because of their purposes. The TSCA program is guided by this section 403 rule, which identifies lead-base paint hazards, which consist of lead paint and lead-containing residential dusts and soils that the Agency considers to be hazards under applicable statutory criteria. Guidance for the OSWER programs is provided by the 1994 Revised Interim Soil Lead (Pb) Guidance for CERCLA Sites and RCRA Corrective Action Facilities (OSWER Directive # 9355.4-12, 1994) and Clarification to the 1994 Revised Interim Soil Lead (Pb) Guidance for CERCLA Sites and RCRA Corrective Action Facilities (OSWER Directive # 9200.4-27P, August 27, 1998) (Refs. 15 and 16).

The EPA programs that implement the RCRA and CERCLA statutes rely on the IEUBK model for relating environmental levels to blood lead levels in children. The OSWER soil lead guidance recommends that the IEUBK Model be applied to utilize site-specific information that can be very important in evaluating the risks at hazardous

waste sites with residential exposure scenarios. This section 403 rule also employs analyses that have relied on the IEUBK Model and the empirical model which employs analyses based on empirical data.

In the absence of site-specific information at hazardous waste sites, EPA believes that soil lead levels above 400 ppm may pose a health risk to children through elevated blood lead levels. The 400 ppm screening level identified in the OSWER soil lead guidance is consistent with both the children's play area hazard determination identified in this rule and the initial candidate hazard level discussed in this preamble. Site-specific information at hazardous waste sites would provide a basis to identify a different soil lead level that would be protective of health. The TSCA soil hazard levels of 400 ppm (play areas) and an average 1,200 ppm (rest of yard) should not be understood as a minimum cleanup level for lead in soils at hazardous waste sites and levels greater than these could be consistent with CERCLA requirements, depending on site-specific factors. Soil lead levels less than these still may pose serious health risks and may warrant timely response actions including abatement. The hazard standard in this TSCA rule was intended as a ''worst first'' level that will aid in setting priorities to address the greatest lead risks promptly at residential and child-occupied facilities affected by lead-based paint.

In contrast with the section 403 rule, which establishes minimum national standards that are designed to be used at millions of residential properties and child-occupied facilities across the nation, the studies that take place at CERCLA or RCRA involve multiple hazardous substances with potentially numerous sources of contamination and multiple pathways of exposure that require that response levels be developed with site-specific information. Other statutory and regulatory criteria that would typically be considered in determining a final clean-up number include: long-term effectiveness and permanence; and reduction of toxicity, mobility, or volume through treatment; short-term effectiveness; implementability; cost; State acceptance; and community acceptance.

V. References

The official record for this rulemaking has been established under docket control number OPPTS–62156, and the public version of the official record is available for inspection as specified in Unit I.B.2. The following is a listing of some of the documents that have been placed in the official record for this rulemaking, including those specifically referenced in this rulemaking.

1. Brody, D.J., J.L. Pirkle, R.A. Kramer, K.M. Flegal, T.D. Matte, E.W. Gutiter, and D.C. Paschal. 1994. ''Blood Lead Levels in the U.S. Population: Phase I of the Third National Health and Nutrition Examination Survey (NHANES III, 1988 to 1991).'' Journal of the American Medical Association. 272(4):277-283.

2. Pirkle, J.L., D.J. Brody, E.W. Gunter, R.A. Kramer, D.C. Paschal, K.M. Flegal, and T.D. Matte. (1994) ''The Decline in Blood Lead Levels in the United States: The National Health and Nutrition Examination Surveys (NHANES).'' Journal of the American Medical Association. 272(4):284-291.

3. CDCP. (1991, October) Preventing Lead Poisoning in Young Children: A Statement by the Centers for Disease Control.

4. CDCP. (1997, February 21) ''Update: Blood Lead Levels-U.S., 1991-1994.'' Morbidity and Mortality Weekly Report. 46(7):141-145.

5. HUD. (1995, June) HUD Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing.

6. HUD. (1995) The Relation of Lead-Contaminated House Dust and Blood Lead Levels Among Urban Children. Volumes I and II. Final report to U.S. HUD from the University of Rochester School of Medicine, Rochester, NY and The National Center for Lead Safe Housing, Columbia, MD.

7. USEPA. (1990, January) ''Report of the Clean Air Scientific Advisory Committee on its Review of the OAQPS Lead Staff Paper and the ECAO Air Quality Criteria Document Supplement.'' EPA-SAB-CASAC-90-002. January.

8. USEPA. (1994) Reducing Lead Hazards When Remodeling Your Home. EPA 747-R-94-002.

9. USEPA, OPPT. (1995, April) Report on the National Survey of Lead Based Paint in Housing - Base Report. EPA 747-R-95-003.

10. USEPA, OPPT. (1995, April). Report on the National Survey of Lead Based Paint in Housing - Appendix II: Analysis. EPA 747-R-95-005.

11. USEPA. (1995, April) Report on the National Survey of Lead-Based Paint in Housing. Appendix I: Design and Methodology. EPA 747-R95-004.

12. USEPA. (1997, December) Risk Analysis to Support Standards for Lead in Paint, Dust, and Soil. Volumes I and II. EPA 747-R-97-006.

13. USEPA. (1998) Economic Analysis of TSCA Section 403: Lead-Based Paint Hazard Standards.

14. USEPA. (2000) Economic Analysis of TSCA Section 403: Lead-Based Paint Hazard Standards.

15. USEPA. (1994) 1994 Revised Interim Soil Lead (Pb) Guidance for CERCLA Sites and RCRA Corrective Action Facilities, OSWER Directive #9355.4-12, 1994.

16. USEPA. (1998, August 27) Clarification to the 1994 Revised Interim Soil Lead (Pb) Guidance for CERCLA Sites and RCRA Corrective Action Facilities, OSWER Directive #9200.4-27P.

17. USEPA. (1996) Urban Soil Lead Abatement Demonstration Project, Volume I: EPA Integrated Report #600/P93/001aF.

VI. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has designated this an ''economically significant regulatory action,'' because this action may result in behavioral changes that involve increased expenditures by owners of target housing and child-occupied facilities, with a potential annual effect on the economy of $100 million or more. Although the establishment of the standards contained in this rule do not, in and of themselves, mandate any action, the Agency recognizes that the existence of the hazard standards may influence the decisions or actions of owners of target housing. This rulemaking was therefore submitted to OMB for review under this Executive Order, and any changes made during that review have been documented in the public version of the official record.

In addition, while EPA does not believe that this action, in and of itself, imposes any requirements, EPA has prepared an economic analysis of the potential impacts of this action, which is contained in a document entitled *Economic Analysis of Toxic Substances Control Act Section 403: Lead-Based Paint Hazard Standards* (Ref.). The Agency believes that, in establishing the standards, it is reasonable to consider the potential costs and benefits associated with the possible actions that an owner could or might take based on the hazard standard. The analysis, in conjunction with other considerations, helped the decision-makers to select the final hazard standards presented in this document. The analysis is available as a part of the public version of the official record for this action and is briefly summarized here.

Building on the economic analysis for the proposed rule (Ref. ?), which is summarized in Unit XII of the proposed rule (63 FR at 30349-30351), the final economic analysis contains one major change. For the final rule, EPA separtely assessed the costs and benefits associated with a separate soil standard for play areas and presented the results in Appendix 7 of the Economic Analysis. The following summary of the economic analysis focuses on this change. A summary of the rest of the analysis was presented in the proposed rule (63 FR at 30349–30351).

In this additional analysis, the revised model goes through a three-step process to estimate which homes might incur a soil abatement and what parts of the yard might be addressed. The first two steps are the same as the original model, a third step was added to address the play area issue. In the original model, if the home's average of near and remote soil concentrations did not exceed the standard, then the model assumed that no soil abatements would occur. In the revised model, if the average soil concentrations were below the soil standard, then the play area (represented by the remote area) soil concentration was compared to the standard. If this alone exceeded the standard, then the model assumed that the play area soil would be removed and replaced.

The Agency notes that the costs presented here for soil response actions are based upon the assumption that those responses would be soil abatement. As noted previously in this preamble, in performing its analyses for this rule, the Agency could not quantitatively compare interim control strategies with abatement strategies because there are only limited data available on the effectiveness of interim controls over extended periods of time, and those data which are available are not suitable for quantitative comparisons with abatements. Nevertheless, experience with interim control programs is increasing and certain organizations, particularly public health and housing agencies, believe they have been able to develop effective programs for interim controls which achieve virtually the same degree of risk reduction as do abatement programs, but at much reduced cost. Thus, to the extent that interim control strategies are used rather than abatement, the actual costs may be different from those presented below.

The play area is assumed to be much smaller than the entire remote area of the yard, and separate soil intervention unit costs were estimated for the play area. The costs assume that the average play area for a single-family home is 200 square feet, and the average play area for a multi-family building is 400 square feet. The play area soil intervention costs are estimated to be: $1,070 for a single-family house ($1,738 if the soil is hazardous), and $1,566 for multi-family buildings ($2,903 if the waste is hazardous). In addition to these soil intervention costs, each home incurs a dust clean-up. Because dust clean-ups are required for certain other interventions, a particular home may already be incurring dust clean-up costs and would not incur a second set of dust clean-up costs.

The total costs (estimated over a 50–year span, and discounted at 3%) for the final dust and soil standards of 40 μg/ft^2 for floor dust, 250 μg/ft^2 for window sill dust and 1,200 ppm for soil, are estimated to be $69 billion, while the total estimated benefits are $192 billion using the IEUBK model and $49 billion using the empirical model, resulting in estimated net benefits of $123 billion using the IEUBK model and $20 billion using the empirical model. About 26.7 million homes are projected to exceed one or more of the standards, and the Agency projected approximately 46.0 million children would experience reduced exposure to household lead in soil, dust, and paint.

B. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The factual basis for the Agency's determination is presented in the small entity impact analysis prepared as part of the economic analysis for this rule (Ref. 14), and is briefly summarized here.

It is important to first note that this rule does not, in and of itself, mandate any action, or directly impose any costs. Nevertheless, since the Agency recognizes that the existence of the hazard standards may influence the decisions or actions of owners of target housing, the Agency has considered the potential costs and benefits associated with the possible actions that a small entity could or might take based on the hazard standard. In addition, EPA has already promulgated several regulations implementing other sections of Title X that use or reference the hazard standards contained in this rule, and also has a few other related regulations under development. In promulgating these regulations, the Agency has and will continue to consider the potential adverse impacts on small entities in the context of those regulations, and in compliance with the RFA. In general, EPA strives to minimize potential adverse impacts on small entities when developing regulations to achieve the environmental and human health protection goals of the statute, and the Agency.

For the purpose of analyzing the potential impacts of this rule on small entities, EPA used the definition for small entities that is found in section 601 of the RFA. Under section 601, ''small entity'' is defined as: (1) A small business that meets Small Business Administration (SBA) size standards codified at 13 CFR 121.201 which uses the NAICS codes to categorize businesses; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. The SBA size standard for the types of small businesses potentially impacted by this rule is $5 million in annual revenues for operators of multi-family housing or apartment buildings (NAICS code 531110 and 531311).

It its analysis, the Agency has assumed that this rule would impact small businesses that engage in lead-based paint activities (i.e., abatement, risk assessment, etc.), small businesses that offer LBP activity related training, small businesses that own or manage rental properties involving target housing, small not-for-profit organizations that are engaged in LBP activities and are not dominant in their field, and small governmental jurisdictions that receive assistance through Federal housing programs (i.e., city and county public housing authorities). By definition, States and Federal agencies are not small.

Based on the analysis, the Agency estimates that approximately 99% of the firms would have less than a 1% impact on revenues due to this rule, and approximately 1% of firms could experience impacts between 1% and 3% of rental revenue. A comparison of annual compliance costs to annual rental income is equivalent to the commonly used ratio of compliance costs to sales. Although the rule could impact a substantial number of small entities, this analysis indicates that the potential impact should not be significant.

Information relating to this determination has been provided to the Chief Counsel for Advocacy of the Small Business Administration upon request,

and is included in the public version of the official record for this rulemaking.

C. Paperwork Reduction Act

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial publication in the **Federal Register**, are maintained in a list at 40 CFR part 9.

This final regulatory action does not contain any information collection requirements that require additional OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* Specifically, States and Tribes with authorized programs under 40 CFR part 745, subpart L will still need to demonstrate their standards for identifying lead-based paint hazards and clearance standards for dust, in the reports that they submit to EPA under 40 CFR 745.324(h). This reporting requirement is contained in the regulations implementing TSCA sections 402(a) and 404, for which the Information Collection Request (ICR) has already been approved by OMB under control number 2070–0155 (EPA ICR No. 1715). As a part of the economic analysis, EPA also re-examined this ICR and determined that the burden estimates provided in the ICR would not change as a result of the promulgation of the standards proposed. Because there are no new information collection requirements to consider, or any changes to the existing requirements that might impact the existing burden estimates, additional OMB review and approval under the PRA is not necessary.

D. Unfunded Mandates Reform Act

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. As indicated previously, this rule does not, in and of itself, mandate any action, or directly impose any costs. Nevertheless, the Agency recognizes that the existence of the hazard standards may influence the decisions or actions of State, local or tribal governmental officials as they relate to lead-based paint activities, i.e., hazard interventions and risk assessments. In addition, EPA has already promulgated several regulations implementing other sections of Title X that use or reference the hazard standards contained in this rule, and has a few other related regulations under development. In promulgating these regulations, the Agency has and will continue to consider the potential impacts on State, local or tribal governments.

The UMRA requirements in sections 202, 204, and 205 do not apply to this rule, because this action does not contain any ''Federal mandates'' or impose any ''enforceable duty'' on State/Tribal, or local governments or on the private sector. The requirements in section 203 do not apply because this rule does not contain any regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final rule does not have federalism implications, because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Although the standards established by this regulation may be adopted by any State, this regulation does not contain any mandates, and will not, therefore, impose any substantial direct costs on States. Nor would the rule substantially affect the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Thus, Executive Order 13132 does not apply to this rule.

Although section 6 of Executive Order 13132 does not apply to this rule, EPA involved State and local governmental agencies in an extensive ''dialogue'' process, which is discussed in more detail in Unit II of the preamble to the proposal (63 FR at 30307). During development of the proposed rule, EPA also consulted with the States at meetings of the Forum on State and Tribal Toxics Action and the annual EPA meeting with State program representatives.

F. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments.

This rule does not significantly or uniquely affect the communities of Indian tribal governments, nor does it impose substantial direct compliance costs on such communities. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

Nevertheless, although tribal governments are not required to administer any of the Lead Programs, the Agency consulted with interested Tribal government representatives as part of the Forum on State and Tribal Toxics Action and EPA's annual national lead meeting with States and tribes. The Agency has also provided extensive technical and financial assistance.

G. Executive Order 12898

Pursuant to Executive Order 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency has considered environmental justice-related issues with regard to the potential impacts of this action on the environmental and health conditions in minority and low-income populations. The Agency's standards will protect children in minority and low-income communities from disproportionate burdens. This is based on the findings of the Agency's economic analysis which shows that non-white populations receive more of the public health benefit associated with the standards.

In addition, EPA consulted with representatives of a variety of interests, including members of environmental justice advocacy groups. The Dialogue Process, which EPA specifically established to provide input into the decision making process, included a low-income parent, two members of the National Environmental Justice Advisory Council, and representatives

of two other groups who spoke on behalf of disadvantaged populations. These individuals comprised 20% of the membership of the process. Moreover, during the public comment period, EPA held two public meetings where residents of low-income communities and representatives of environmental justice groups offered public comment to EPA. The Agency also received written comments from 50 groups and several hundred individuals raising environmental justice concerns. Consequently, EPA believes that it has complied with the provision of the executive order to provide representatives of environmental justice interests to participate fully in the process and to provide input and comment to the Agency.

Furthermore, recognizing that these standards would be used by and affect millions of people that do not have a comprehensive understanding of the science of lead hazards, EPA made a conscious decision to make the standards simple. For example, instead of joint standards that might have better reflected overall risk under some circumstances, EPA chose to establish media-specific standards because they are easier to understand and use. Outreach documents (e.g, fact sheets) are written and designed with the specific objective of making the regulation easy for the public to understand. In addition, EPA's broader lead outreach program includes extensive elements that specifically target non-white and low income communities.

H. Executive Order 13045

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), applies to this rule because OMB has determined that this rule is ''economically significant'' as defined under Executive Order 12866 (see Unit VI.A.). In addition, the environmental health or safety risk addressed by this rule may have a disproportionate affect on children.

In accordance with section 5(501) of Executive Order 13045, EPA has evaluated the environmental health or safety effects of lead-based paint on children in the selection of the hazard standards contained in this rule. The results of this evaluation are contained in the ''Risk Analysis to Support Standards for Lead in Paint, Dust, and Soil'' and the supplement to this analysis. Copies of these documents have been placed in the public version of the official record for this rule. This analysis focused almost exclusively on assessing exposure and risk to young children.

Moreover, the standards selected by EPA are designed first and foremost to protect children from lead in residential paint, dust, and soil. In this regard, EPA believes that it has selected the most protective standards possible. Although the Agency could have selected numerically more stringent standards, EPA concluded that more stringent standards would afford less protection to children because EPA believes that limited resources would be diluted and possibly diverted from children who are at greatest risk. The standards will also protect children by supporting implementation of other provisions of the national lead program, such as hazard disclosure prior to the sale or rental of most pre-1978 housing and evaluation and control of lead-based paint hazards and Federally-assisted and Federally owned housing prior to disposition.

I. National Technology Transfer and Amendment Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The Agency has determined that there are no voluntary consensus standards for lead-based paint hazards. However, the Agency has, where appropriate, referred to voluntary consensus standards developed by such organizations as the American Society for Testing and Materials (ASTM) with respect to sampling and analytical methods.

J. Executive Order 12630

EPA has complied with Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988), by examining the takings implications of this rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the Executive Order.

K. Executive Order 12988

In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

VII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a major rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States. This rule is a ''major rule'' as defined by 5 U.S.C. 804(2). A major rule cannot take effect until 60 days after date it is published in the **Federal Register** or is submitted to Congress whichever is later. This rule will take effect on March 6, 2001.

List of Subjects in 40 CFR Part 745

Environmental protection, Hazardous substances, Lead poisoning, Reporting and recordkeeping requirements.

Dated: December 22, 2000.

Carol M. Browner,

Administrator.

Therefore, 40 CFR part 745 is amended as follows:

PART 745—AMENDED

1. The authority citation for part 745 continues to read as follows:

Authority: 15 U.S.C. 2605, 2607, 2681–2692 and 42 U.S.C. 4852d.

2. By adding new subpart D to read as follows:

Subpart D—Lead-Based Paint Hazards

Sec.

Subpart D—Lead-Based Paint Hazards

§ 745.61 Scope and applicability.

(a) This subpart identifies lead-based paint hazards.

(b) The standards for lead-based paint hazards apply to target housing and child-occupied facilities.

(c) Nothing in this subpart requires the owner of property(ies) subject to these standards to evaluate the property(ies) for the presence of lead-based paint hazards or take any action to control these conditions if one or more of them is identified.

§ 745.63 Definitions.

The following definitions apply to part 745.

Arithmetic mean means the algebraic sum of data values divided by the number of data values (e.g., the sum of the concentration of lead in several soil samples divided by the number of samples).

Chewable surface means an interior or exterior surface painted with lead-based paint that a young child can mouth or chew. A chewable surface is the same as an ''accessible surface'' as defined in 42 U.S.C. 4851b(2)). Hard metal substrates and other materials that cannot be dented by the bite of a young child are not considered chewable.

Common area group means a group of common areas that are similar in design, construction, and function. Common area groups include, but are not limited to hallways, stairwells, and laundry rooms.

Concentration means the relative content of a specific substance contained within a larger mass, such as the amount of lead (in micrograms per gram or parts per million by weight) in a sample of dust or soil.

Deteriorated paint means any interior or exterior paint or other coating that is peeling, chipping, chalking or cracking, or any paint or coating located on an interior or exterior surface or fixture that is otherwise damaged or separated from the substrate.

Dripline means the area within 3 feet surrounding the perimeter of a building.

Friction surface means an interior or exterior surface that is subject to abrasion or friction, including, but not limited to, certain window, floor, and stair surfaces.

Impact surface means an interior or exterior surface that is subject to damage by repeated sudden force such as certain parts of door frames.

Interior window sill means the portion of the horizontal window ledge that protrudes into the interior of the room.

Lead-based paint hazard means hazardous lead-based paint, dust-lead hazard or soil-lead hazard as identified in § 745.65.

Loading means the quantity of a specific substance present per unit of surface area, such as the amount of lead in micrograms contained in the dust collected from a certain surface area divided by the surface area in square feet or square meters.

Mid-yard means an area of a residential yard approximately midway between the dripline of a residential building and the nearest property boundary or between the driplines of a residential building and another building on the same property.

Play area means an area of frequent soil contact by children of less than 6 years of age as indicated by, but not limited to, such factors including the following: the presence of play equipment (e.g., sandboxes, swing sets, and sliding boards), toys, or other children's possessions, observations of play patterns, or information provided by parents, residents, care givers, or property owners.

Residential building means a building containing one or more residential dwellings.

Room means a separate part of the inside of a building, such as a bedroom, living room, dining room, kitchen, bathroom, laundry room, or utility room. To be considered a separate room, the room must be separated from adjoining rooms by built-in walls or archways that extend at least 6 inches from an intersecting wall. Half walls or bookcases count as room separators if built-in. Movable or collapsible partitions or partitions consisting solely of shelves or cabinets are not considered built-in walls. A screened in porch that is used as a living area is a room.

Soil sample means a sample collected in a representative location using ASTM E1727, ''Standard Practice for Field Collection of Soil Samples for Lead Determination by Atomic Spectrometry Techniques,'' or equivalent method.

Weighted arithmetic mean means the arithmetic mean of sample results weighted by the number of subsamples in each sample. Its purpose is to give influence to a sample relative to the surface area it represents. A single surface sample is comprised of a single subsample. A composite sample may contain from two to four subsamples of the same area as each other and of each single surface sample in the composite. The weighted arithmetic mean is obtained by summing, for all samples, the product of the sample's result multiplied by the number of subsamples in the sample, and dividing the sum by the total number of subsamples contained in all samples. For example, the weighted arithmetic mean of a single surface sample containing 60 $\mu g/ft^2$, a composite sample (three subsamples) containing 100 $\mu g/ft^2$, and a composite sample (4 subsamples) containing 110 $\mu g/ft^2$ is 100 $\mu g/ft^2$. This result is based on the equation [60+(3*100)+(4*110)]/(1+3+4).

Window trough means, for a typical double-hung window, the portion of the exterior window sill between the interior window sill (or stool) and the frame of the storm window. If there is no storm window, the window trough is the area that receives both the upper and lower window sashes when they are both lowered. The window trough is sometimes referred to as the window ''well.''

Wipe sample means a sample collected by wiping a representative surface of known area, as determined by ASTM E1728, ''Standard Practice for Field Collection of Settled Dust Samples Using Wipe Sampling Methods for Lead Determination by Atomic Spectrometry Techniques, or equivalent method, with an acceptable wipe material as defined in ASTM E 1792, ''Standard Specification for Wipe Sampling Materials for Lead in Surface Dust.''

§ 745.65 Lead-based paint hazards.

(a) *Paint-lead hazard.* A paint-lead hazard is any of the following:

(1) Any lead-based paint on a friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface underneath the friction surface (e.g., the window sill, or floor) are equal to or greater than the dust-lead hazard levels identified in paragraph (b) of this section.

(2) Any damaged or otherwise deteriorated lead-based paint on an impact surface that is caused by impact from a related building component (such as a door knob that knocks into a wall or a door that knocks against its door frame.

(3) Any chewable lead-based painted surface on which there is evidence of teeth marks.

(4) Any other deteriorated lead-based paint in any residential building or child-occupied facility or on the exterior of any residential building or child-occupied facility.

(b) *Dust-lead hazard.* A dust-lead hazard is surface dust in a residential dwelling or child-occupied facility that contains a mass-per-area concentration of lead equal to or exceeding 40 $\mu g/ft^2$ on floors or 250 $\mu g/ft^2$ on interior window sills based on wipe samples.

(c) *Soil-lead hazard.* A soil-lead hazard is bare soil on residential real property or on the property of a child-occupied facility that contains total lead equal to or exceeding 400 parts per million ($\mu g/g$) in a play area or average of 1,200 parts per million of bare soil in the rest of the yard based on soil samples.

(d) *Work practice requirements.* Applicable certification, occupant protection, and clearance requirements and work practice standards are found in regulations issued by EPA at 40 CFR part 745, subpart L and in regulations issued by the Department of Housing and Urban Development (HUD) at 24 CFR part 35, subpart R. The work practice standards in those regulations do not apply when treating paint-lead hazards of less than:

(1) Two square feet of deteriorated lead-based paint per room or equivalent,

(2) Twenty square feet of deteriorated paint on the exterior building, or

(3) Ten percent of the total surface area of deteriorated paint on an interior or exterior type of component with a small surface area.

3. In § 745.223, by removing the definitions for ''Lead-contaminated dust'' and ''Lead-contaminated soil,'' and by revising paragraph (1) of the definition of ''Abatement,'' to read as follows:

§ 745.223 Definitions.

* * * * *

Abatement * * *

(1) The removal of paint and dust, the permanent enclosure or encapsulation of lead-based paint, the replacement of painted surfaces or fixtures, or the removal or permanent covering of soil, when lead-based paint hazards are present in such paint, dust or soil; and

* * * * *

4. In § 745.227, by revising paragraphs (d)(4), (d)(5), (d)(6) introductory text, (d)(7), (e)(7)(i), (e)(7)(ii), (e)(8)(ii), (e)(8)(v)(A), (e)(8)(v)(B), (e)(8)(vii), by redesignating paragraph (d)(8)(ii) as paragraph (d)(8)(iii) and paragraph (h) as paragraph (i), and by adding paragraphs (d)(8)(ii), (e)(8)(viii), and (h) to read as follows:

§ 745.227 Work practice standards for conducting lead-based paint activities: target housing and child-occupied facilities.

* * * * *

(d) * * *

(4) The following surfaces which are determined, using documented methodologies, to have a distinct painting history, shall be tested for the presence of lead:

(i) Each friction surface or impact surface with visibly deteriorated paint; and

(ii) All other surfaces with visibly deteriorated paint.

(5) In residential dwellings, dust samples (either composite or single-surface samples) from the interior window sill(s) and floor shall be collected and analyzed for lead concentration in all living areas where one or more children, age 6 and under, are most likely to come into contact with dust.

(6) For multi-family dwellings and child-occupied facilities, the samples required in paragraph (d)(4) of this section shall be taken. In addition, interior window sill and floor dust samples (either composite or single-surface samples) shall be collected and analyzed for lead concentration in the following locations:

* * * * *

(7) For child-occupied facilities, interior window sill and floor dust samples (either composite or single-surface samples) shall be collected and analyzed for lead concentration in each room, hallway or stairwell utilized by one or more children, age 6 and under, and in other common areas in the child-occupied facility where one or more children, age 6 and under, are likely to come into contact with dust.

(8) * * *

(ii) The rest of the yard (i.e., non-play areas) where bare soil is present.

* * * * *

(e) * * *

(7) * * *

(i) If the soil is removed:

(A) The soil shall be replaced by soil with a lead concentration as close to local background as practicable, but no greater than 400 ppm.

(B) The soil that is removed shall not be used as top soil at another residential property or child-occupied facility.

(ii) If soil is not removed, the soil shall be permanently covered, as defined in § 745.223.

(8) * * *

(ii) Following the visual inspection and any post-abatement cleanup required by paragraph (e)(8)(i) of this section, clearance sampling for lead in dust shall be conducted. Clearance sampling may be conducted by employing single-surface sampling or composite sampling techniques.

* * * * *

(v) * * *

(A) After conducting an abatement with containment between abated and unabated areas, one dust sample shall be taken from one interior window sill and from one window trough (if present) and one dust sample shall be taken from the floors of each of no less than four rooms, hallways or stairwells within the containment area. In addition, one dust sample shall be taken from the floor outside the containment area. If there are less than four rooms, hallways or stairwells within the containment area, then all rooms, hallways or stairwells shall be sampled.

(B) After conducting an abatement with no containment, two dust samples shall be taken from each of no less than four rooms, hallways or stairwells in the residential dwelling or child-occupied facility. One dust sample shall be taken from one interior window sill and window trough (if present) and one dust sample shall be taken from the floor of each room, hallway or stairwell selected. If there are less than four rooms, hallways or stairwells within the residential dwelling or child-occupied facility then all rooms, hallways or stairwells shall be sampled.

* * * * *

(vii) The certified inspector or risk assessor shall compare the residual lead level (as determined by the laboratory analysis) from each single surface dust sample with clearance levels in paragraph (e)(8)(viii) of this section for lead in dust on floors, interior window sills, and window troughs or from each composite dust sample with the applicable clearance levels for lead in dust on floors, interior window sills, and window troughs divided by half the number of subsamples in the composite sample. If the residual lead level in a single surface dust sample equals or exceeds the applicable clearance level or if the residual lead level in a composite dust sample equals or exceeds the applicable clearance level divided by half the number of subsamples in the composite sample, the components represented by the failed sample shall be recleaned and retested.

(viii) The clearance levels for lead in dust are 40 $\mu g/ft^2$ for floors, 250 $\mu g/ft^2$ for interior window sills, and 400 $\mu g/ft^2$ for window troughs.

* * * * *

(h) *Determinations.* (1) Lead-based paint is present:

(i) On any surface that is tested and found to contain lead equal to or in excess of 1.0 milligrams per square centimeter or equal to or in excess of 0.5% by weight; and

(ii) On any surface like a surface tested in the same room equivalent that has a similar painting history and that is found to be lead-based paint.

(2) A paint-lead hazard is present:

(i) On any friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface underneath the friction surface (e.g., the window sill or floor) are equal to or greater than the dust hazard levels identified in § 745.227(b);

(ii) On any chewable lead-based paint surface on which there is evidence of teeth marks;

(iii) Where there is any damaged or otherwise deteriorated lead-based paint on an impact surface that is cause by

impact from a related building component (such as a door knob that knocks into a wall or a door that knocks against its door frame; and

(iv) If there is any other deteriorated lead-based paint in any residential building or child-occupied facility or on the exterior of any residential building or child-occupied facility.

(3) A dust-lead hazard is present in a residential dwelling or child occupied facility:

(i) In a residential dwelling on floors and interior window sills when the weighted arithmetic mean lead loading for all single surface or composite samples of floors and interior window sills are equal to or greater than 40 μg/ft^2 for floors and 250 μg/ft^2 for interior window sills, respectively;

(ii) On floors or interior window sills in an unsampled residential dwelling in a multi-family dwelling, if a dust-lead hazard is present on floors or interior window sills, respectively, in at least one sampled residential unit on the property; and

(iii) On floors or interior window sills in an unsampled common area in a multi-family dwelling, if a dust-lead hazard is present on floors or interior window sills, respectively, in at least one sampled common area in the same common area group on the property.

(4) A soil-lead hazard is present:

(i) In a play area when the soil-lead concentration from a composite play area sample of bare soil is equal to or greater than 400 parts per million; or

(ii) In the rest of the yard when the arithmetic mean lead concentration from a composite sample (or arithmetic mean of composite samples) of bare soil from the rest of the yard (i.e., non-play areas) for each residential building on a property is equal to or greater than 1,200 parts per million.

5. In § 745.325, by revising paragraphs (d)(2)(iii)(A) and (d)(2)(iii)(B), by redesignating (d)(2)(iv) and (d)(2)(v) as (d)(2)(v) and (d)(2)(vi), respectively, and by adding paragraphs (d)(2)(iii)(C), (d)(2)(iii)(D), (d)(2)(iv), and (e), to read as follows:

§ 745.325 Lead-based paint activities: State and Tribal program requirements.

* * * * *

(d) * * *

(2) * * *

(iii) * * *

(A) An assessment, including a visual inspection, of the physical characteristics of the residential dwelling or child-occupied facility;

(B) Environmental sampling for lead in paint, dust, and soil;

(C) Environmental sampling requirements for lead in paint, dust, and soil that allow for comparison to the standards for lead-based paint hazards established or revised by the State or Indian Tribe pursuant to paragraph (e) of this section; and

(D) A determination of the presence of lead-based paint hazards made by comparing the results of visual inspection and environmental sampling to the standards for lead-based paint hazards established or revised by the State or Indian Tribe pursuant to paragraph (e) of this section.

(iv) The program elements required in paragraph (d)(2)(iii)(C) and (d)(2)(iii)(D) of this section shall be adopted in accordance with the schedule for the demonstration required in paragraph (e) of this section.

* * * * *

(e) The State or Indian Tribe must demonstrate that it has standards for identifying lead-based paint hazards and clearance standards for dust, that are at least as protective as the standards in § 745.227 as amended on February 5, 2001. A State or Indian Tribe with such a section 402 program approved before February 5, 2003 shall make this demonstration no later than the first report submitted pursuant to § 745.324(h) on or after February 5, 2003. A State or Indian Tribe with such a program submitted but not approved before February 5, 2003 may make this demonstration by amending its application or in its first report submitted pursuant to § 745.324(h). A State or Indian Tribe submitting its program on or after February 5, 2003 shall make this demonstration in its application.

[FR Doc. 01–84 Filed 1–4–01; 8:45 am]

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Federal Register

Friday,

January 5, 2001

Part IV

Environmental Protection Agency

40 CFR Part 180

Methyl Parathion; Notice of Pesticide Tolerance Revocations; Final Rule

Department of Health and Human Services

Food and Drug Administration

Final Guidance for Industry: Channels of Trade Policy for Commodities with Methyl Parathion Residues; Availability; Notice

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301076; FRL–6752–6]

RIN 2070– AB78

Methyl Parathion; Notice of Pesticide Tolerance Revocations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency previously published in the **Federal Register** a proposed rule, proposing to revoke methyl parathion tolerances for several commodities. This document announces the revocation of tolerances for the insecticide methyl parathion on the following commodities: Apples, artichokes, beets (greens alone), beets (with or without tops), birdsfoot trefoil forage, birdsfoot trefoil hay, broccoli, Brussels sprouts, carrots, cauliflower, celery, cherries, collards, grapes, kale, lentils, kohlrabi, lettuce, mustard green, nectarines, peaches, pears, plums (fresh prunes), rutabagas (with or without tops), rutabaga tops, spinach, tomatoes, turnips (with or without tops), turnips greens, vegetables leafy Brassica (cole), and vetch. Additionally, EPA is amending the following tolerances: beans (amend to beans, dried), peas (amend to peas, dried) so that methyl parathion is not used on succulent beans and peas. Note that methyl parathion may still be used on lentils; however, residues on lentils are covered by the tolerance for peas, dried. Foods legally treated with methyl parathion may continue to be marketed under the provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). The regulatory actions in this document are part of the Agency's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the tolerance reassessment requirements of the FFDCA. By law, EPA is required to reassess 66% of the tolerances in existence on August 2, 1996, by August 2002, or about 6,400 tolerances. These tolerances were established under section 408 of the FFDCA, 21 U.S.C. 346a. EPA is revoking these tolerances because the Agency has canceled the pesticide registrations under FIFRA, 7 U.S.C. 136 *et seq.*, associated with them.

DATES: This regulation is effective January 5, 2001. Objections and requests for hearings, identified by docket control number OPP–301076, must be received by EPA on or before March 6, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301076 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: Laura Parsons, Special Review and Registration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: 703–305–5776 and e-mail address: parsons.laura@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Animal production Food manufacturing pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301076. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background

A. What Action is the Agency Taking?

In August 1999, the methyl parathion registrants submitted requests to voluntarily cancel registration of products containing methyl parathion for certain uses as the result of an agreement reached between EPA and the registrants. Given the risks associated with use of methyl parathion under the existing terms and conditions of use, EPA granted the requests for voluntary cancellation. On October 27, 1999, EPA published a notice in the **Federal Register** (64 FR 578771) (FRL–6387–8) announcing the cancellation of all methyl parathion uses on fruits and most uses on vegetables. The notice of voluntary cancellation, the date of allowable use, and the intent to revoke the methyl parathion tolerances were widely publicized. USDA sent notification to our trading partners through the World Trade Organization notification procedures. EPA also notified the regulatory authorities in over 145 countries as per FIFRA 17(b). For the canceled uses, existing stock of methyl parathion was allowed to be used until December 31, 1999.

On August 2, 1999 the EPA Administrator stated that while the current food supply is safe, the

cancellation of certain uses of methyl parathion makes the food supply safer. This action is part of EPA's overall effort to reduce risks to the food supply under the Congressional mandate imposed by FQPA.

B. Comments Received on Proposed Revocation

In the **Federal Register** of June 2, 2000 (65 FR 35307) (FRL–6491–9), EPA issued a proposed rule to revoke the tolerances listed in this final rule. In response to this document, nine parties submitted comments. Comments were received from Knouse Foods, Minor Crop Farmer Alliance, National Food Processors Association, The California Pistachio Commission, Elf Atochem, The Almond Hullers and Processors Association, Consultants in Toxicology, Risk Assessment and Product Safety (CTRAPS), The European Commission, and Jellinek, Swartz and Connelly representing the registrant, Cheminova.

Seven of the commenters addressed one or both of two issues. The first is whether the FQPA section 408(l)(2), which requires revocation of tolerances for dietary risk based cancellations within 180 days of the last legal use, applies to voluntary cancellations. The methyl parathion registrants agreed upon use cancellations after considering the dietary risk assessment which showed unacceptably high levels of methyl parathion in foods. The commenters stated that ''Congress did not intend for 408 (l)(2) to apply to voluntary cancellations.''

Response. EPA interprets 408(l)(2) of FDCA to apply to both cancellations effected through FIFRA 6(f) (voluntary action by a registrant) and those effected through FIFRA 6(b) (an Agency initiated cancellation action), provided that the cancellation is related to dietary risk. The Agency would point out that most cancellations are voluntary in nature, even when related to dietary risk, and we believe that congressional intent was to provide guidance on how to handle the majority of cases.

The second issue is that not all of the uses contributed to the dietary risk and therefore, only tolerances which contribute heavily to dietary risk should be included in the 408(l)(2) revocation.

Response. The Agency agrees that certain uses contributed more heavily towards dietary risk to children than other uses; in fact, certain uses considered alone exceeded the allowable dietary level. However, since the Agency is concerned with risk which is aggregated from all dietary sources, it is not possible to separate particular tolerances as exempt from 408(l)(2) because their contribution to dietary risk is less than from other commodities.

Two additional comments were received. The European Union comment addressed the timing of the action and requested that the Agency postpone this action until after the JMPR Codex Review of methyl parathion scheduled for the autumn of 2000 so as to not give the appearance that this is ''an emergency action.''

Response. While the Agency agrees that the tolerance revocation is not an emergency situation, the Agency is required to take this action in accordance with the timing requirements of FFDCA section 408(l)(2).

Consultants in Toxicology, Risk Assessment and Product Safety submitted a comment addressing the methodology of the methyl parathion risk assessment suggesting that the Agency should follow a degradate of methyl parathion, p-nitrophenol, in the general population instead of trying to predict dietary exposures from residues on food items.

Response. P-nitrophenol is metabolized from several pharmaceutical and pesticidal compounds, including methyl parathion. EPA prefers to use risk assessment methodologies which are as specific to the compound as possible in order to accurately characterize the risk.

C. Comments Received on Other Issues Relating to the Methyl Parathion Cancellation.

The **Federal Register** proposal ((65 FR 35307, June 2, 2000) (FRL 6491–9) Methyl Parathion; Notice of Proposed Tolerance Revocations and Channels of Trade Provision Guidance) also sought comment on alternate approaches for avoiding any potential problems to commerce or trade caused by revocation of these tolerances, and also provided an opportunity for interested parties to comment on the methyl parathion registrants requests to cancel various methyl parathion uses. No comments were received which addressed either of these issues.

D. What is the Agency's Authority for Taking this Action?

A ''tolerance'' represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities (RACs) and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, as amended by the FQPA of 1996, Public Law 104–170, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on RACs and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore, ''adulterated'' under section 402(a) of the FFDCA. 21 U.S.C. 342(a). FFDCA section 301 prohibits, among other things, introduction or delivery for introduction into interstate commerce of any adulterated food. 21 U.S.C. 331(a). For a food–use pesticide to be sold and distributed, the pesticide must be registered under section 3, section 5, or section 18 of FIFRA (7 U.S.C. *et seq.*) Food–use pesticides not registered in the United States may have tolerances for residues of such pesticides in or on commodities imported into the United States provided that EPA has determined that the tolerance is safe under section 408.

Monitoring and enforcement of pesticide tolerances and exemptions are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). This includes monitoring for pesticide residues in or on commodities imported into the United States.

E. When do These Actions Become Effective?

The tolerance revocation is effective on January 5, 2001.

Any commodities listed in the regulatory text of this document that are treated with methyl parathion, and that are in the channels of trade following the tolerance revocations, shall be subject to FFDCA section 408(l)(5), the ''channels of trade provision'' as established by the FQPA. Under this section, any residue of methyl parathion in or on such commodities shall not render the commodities adulterated so long as it is shown to the satisfaction of FDA that, (1) the residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and (2) the residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from a tolerance. The channels of trade provision allows for the orderly marketing of foods that may currently contain legal residues resulting from lawful applications of methyl parathion.

F. What Action is FDA Taking with Respect to the Tolerance Revocation?

The FDA in a related notice published elsewhere in this issue of the **Federal Register** is announcing the availability of a guidance document presenting FDA's policy on its planned enforcement approach for foods

containing methyl parathion residues. This guidance will assist firms in understanding the types of showing under section 408(l)(5) of the FFDCA that FDA may find satisfactory in accordance with its planned enforcement approach for such section.

G. What is the Contribution to Tolerance Reassessment?

By law, EPA is required to reassess 66% or about 6,400 of the tolerances in existence on August 2, 1996, by August 2002. EPA is also required to assess the remaining tolerances by August, 2006. As of April 25, 2000, EPA has assessed over 3,471 tolerances. This document removes 1 (the tolerance for lentils which is covered by the tolerance for peas, dried) and revokes 30 methyl parathion tolerances. However, 27 of these 30 tolerances are expressed as parathion which, as previously defined, may be either ethyl parathion or methyl parathion (this rule redefines those tolerances to include only ethyl parathion); only 3 of the 30 tolerances are methyl parathion alone. Therefore, three tolerances will be counted among reassessments made toward the August, 2002 review deadline of FFDCA section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996.

III. Are There Any International Trade Issues Raised by this Final Action?

EPA is working to ensure that the U.S. tolerance reassessment program under FQPA does not disrupt international trade. EPA considers codex maximum residue limits (MRLs) in setting U.S. tolerances and in reassessing them. MRLs are established by the Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. When possible, EPA seeks to harmonize U.S. tolerances with Codex MRLs. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain in a **Federal Register** document the reasons for departing from the Codex level. EPA's effort to harmonize with Codex MRLs is summarized in the tolerance reassessment section of individual reregistration eligibility decision documents or other documents which reassess tolerances. The U.S. EPA has developed guidance concerning submissions for import tolerance support. This guidance will be made available to interested persons.

IV. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301076 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 6, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Objection/hearing fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IV.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301076, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account

uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

V. Regulatory Assessment Requirements

This final rule will revoke tolerances under FFDCA section 408. The Office of Management and Budget (OMB) has exempted this type of action, i.e. a tolerance revocations for which extraordinary circumstances do not exist, from review under Executive Order 12866, entitled *Regulatory Planning and Review* October 4, 1993 (58 FR 51735). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* May 19, 1998 (63 FR 27655); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low–Income Populations* February 16, 1994 (59 FR 7629); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* April 23, 1997 (62 FR 19885). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency previously assessed whether revocations of tolerances might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. This analysis was published on December 17, 1997 (62 FR 66020), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this rule, the EPA certifies that this action will not have a significant economic impact on a substantial number of small entities. Specifically, as per the 1997 notice, EPA has reviewed its available data on imports and foreign pesticide usage and concludes that there will not be a significant economic impact on a substantial number of small produce importing businesses. Furthermore, the Agency knows of no extraordinary circumstances that exist as to the present revocation that would change EPA's previous analysis.

In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* August 10, 1999 (64 FR 43255). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register.** This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 20, 2000.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. Section 180.121 is revised to read as follows:

§180.121 Parathion or its methyl homolog; tolerances for residues

(a) *General.* (1) Tolerances are established for residues of the insecticide parathion (*O, O*-Diethyl-*O*-*p*-nitrophenyl thiophosphate) or its methyl homolog in or on the following food commodities:

Commodity	Parts per million
Alfalfa (fresh)	1.25
Alfalfa (hay)	5
Almonds	0.1
Almond hulls	3
Apricots	1
Avocados	1
Barley	1
Beans, dried	1
Beets, sugar	0.1
Beets,sugar, (tops)	0.1
Blackberries	1
Blueberries (huckleberries)	1
Boysenberries	1
Cabbage	1
Clover	1
Corn	1
Corn, forage	1
Cotton, seed	0.75
Cranberries	1
Cucumbers	1
Currants	1
Dates	1
Dewberries	1
Eggplants	1
Endive (escarole)	1
Figs	1
Filberts	0.1
Garlic	1
Gooseberries	1
Grass (forage)	1
Guavas	1
Hops	1
Mangos	1
Melons	1
Mustard seed	0.2
Oats	1
Okra	1
Olives	1
Onions	1
Parsnips (with or without tops)	1
Parsnipgreens (alone)	1

Commodity	Parts per million
Peanuts	1
Peas, dried	1
Pea, forage	1
Pecans	0.1
Peppers	1
Pineapples	1
Potatoes	0.1
Pumpkins	1
Quinces	1
Radish (with or without tops)	1
Radish (tops)	1
Rape, seed	0.2
Raspberries	1
Rice	1
Safflower seed	0.1
Sorghum	0.1
Sorghum, fodder	3
Sorghum forage	3
Soybeans	0.1
Soybean hay	1
Squash	1
Strawberries	1
Summer squash	1
Sunflower seed	0.2
Sweet potatoes	0.1
Swiss chard	1
Walnuts	0.1
Wheat	1
Youngberries	1

(2) Tolerances are established for residues of the insecticide parathion *O, O*-Dimethyl-*O-p*-nitrophenyl thiophosphate (the methyl homolog of parathion) in or on the following RACs:

Commodity	Parts per million
Guar beans	0.2
Parsley	1

(3) Tolerances are established for residues of the insecticide parathion *O, O*-Diethyl-*O-p*-nitrophenyl thiophosphate (ethyl parathion) in or on the following RACs:

Commodity	Parts per million
Apples	1
Artichokes	1
Beets greens (alone)	1
Beets (with or without tops)	1
Broccoli	1
Brussels sprouts	1
Carrots	1
Cauliflower	1
Celery	1
Cherries	1
Collards	1
Grapes	1
Kale	1
Kohlrabi	1
Lettuce	1
Mustard green	1
Nectarines	1
Peaches	1
Pears	1
Plums (fresh prunes)	1
Rutabagas(with or without tops)	1
Rutabaga tops	1
Spinach	1
Tomatoes	1
Turnips (with or without tops)	1
Turnips greens	1
Vetch	1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

(e) *Revoked tolerances subject to the channel of trade provisions.* The following table lists commodities for which methyl parathion use was unlawful after December 31, 1999, and the revoked tolerances. Commodities with residues of methyl parathion resulting from lawful use are subject to the channels of trade provisions of section 408(1)(5) of the FFDCA.

Commodity	Parts per million
Apples	1
Artichokes	1
Beets greens (alone)	1
Beets (with or without tops)	1
Birdsfoot trefoil (forage)	1.25
Birdsfoot trefoil (hay)	5
Broccoli	1
Brussels sprouts	1
Carrots	1
Cauliflower	1
Celery	1
Cherries	1
Collards	1
Grapes	1
Kale	1
Kohlrabi	1
Lettuce	1
Mustard green	1
Nectarines	1
Peaches	1
Peaches	1
Pears	1
Plums (fresh prunes)	1
Rutabagas (with or without tops)	1
Rutabaga tops	1
Spinach	1
Tomatoes	1
Turnips (with or without tops)	1
Turnips greens	1
Vegetables leafy Brassica (cole)	1
Vetch	1

[FR Doc. 01–367 Filed 1–4–01; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1309]

Final Guidance for Industry: Channels of Trade Policy for Commodities With Methyl Parathion Residues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled ''Channels of Trade Policy for Commodities with Methyl Parathion Residues.'' This guidance presents FDA's policy for implementing the channels of trade provision for the pesticide chemical methyl parathion in section 408(l)(5) of the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food Quality Protection Act (FQPA) of 1996. The final guidance is intended to assist firms in understanding FDA's planned approach to the enforcement of this provision of the FQPA with regard to residues of methyl parathion in food.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the final guidance to the Office of Plant and Dairy Foods and Beverages (HFS–305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5321, FAX 202–205–4422, e-mail: mkashtoc@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of June 2, 2000 (65 FR 35376), FDA announced the availability of a draft version of this guidance for industry entitled ''Channels of Trade Policy for Commodities with Methyl Parathion Residues.'' The agency has finalized that draft guidance after considering the five comments that were received on the draft version.

In response to a suggestion in a comment, FDA is specifying in this final guidance, the method it intends to use to test for methyl parathion residues in foods. In response to comments asking for additional time and stating that firms need additional time to prepare to make showings, FDA is providing responsible parties with an additional 6 months, i.e., until July 1, 2001, to prepare, e.g., by compiling records, to make a showing to FDA to demonstrate that a processed food is within the scope of FDA's exercise of its enforcement discretion set forth in this guidance.

Several comments addressed the approach FDA stated it intended to follow if it were to find residues of methyl parathion in multiple ingredient foods for which all ingredients are subject to the current Environmental Protection Agency (EPA) methyl parathion tolerance revocation action, e.g., an apple-pear juice. The comments stated that the approach taken in the draft is not consistent with current FDA policy in a related situation regarding pesticide residues in multiple ingredient foods. Under existing FDA policy, if FDA finds a pesticide residue in a multiple ingredient food, e.g., mixed vegetables, in which there is a tolerance for the pesticide in some, but not all of the ingredients, FDA does not ask the responsible firm to demonstrate that the residue is not present in any of the ingredients for which there is no tolerance.

In response to these comments, FDA is revising its planned approach in this final guidance. If FDA finds a residue of methyl parathion in such a multiple ingredient food, e.g., apple-pear juice, to be within the scope of FDA's exercise of enforcement discretion, the responsible party should demonstrate that at least one of the food's ingredients could bear the methyl parathion residue as a result of a lawful application or use of this pesticide chemical. However, if the responsible party makes that showing, FDA does not intend to ask the responsible party to provide additional documentation showing that other ingredients in the food were not the source of the residue of methyl parathion.

FDA has also added additional examples in the final guidance on the approach it intends to follow if it finds methyl parathion residues in multiple ingredient foods in which some ingredients are subject to the current EPA methyl parathion tolerance revocation action and other ingredients are subject to tolerances that remain in effect or are not subject to a tolerance at all.

A comment asked if FDA considered whether methyl parathion could persist in the soil and transfer into crops grown after legal application of this pesticide was terminated by EPA. FDA has worked closely with EPA in developing this guidance, and EPA has given no indication to FDA that residues of methyl parathion persist in the environment such that a food could contain residues of methyl parathion resulting from the application of this pesticide to a previously grown crop. Thus, FDA intends to assume that any residue of methyl parathion found on a food results from application of the pesticide to the crop used to produce the analyzed food.

In response to a request in a comment, FDA, in the final guidance, has provided an example of a situation whereby FDA could come to possess information indicating that there is a reasonable possibility that a residue, that is within the former tolerance, resulted from application of the pesticide to the crop after December 31, 1999, which would constitute an unlawful use of methyl parathion.

Finally, in response to comments expressing concern that food retailers would reject food rather than accept the potential burden of making a showing as the ''responsible party,'' the agency advises that under its compliance program for pesticide residues in domestic foods (FDA monitors pesticide residues in both raw agricultural commodities and processed foods in interstate commerce under this program), samples for routine monitoring purposes are generally not collected at the retail level. The program directs that growers or packing sheds are the preferred sites for sampling fruits and vegetables. Thus, FDA does not expect that in the normal course of business, retailers will be in the role of the ''responsible party'' under this policy.

This final guidance is being issued as a level 1 guidance, consistent with FDA's policy for good guidance practices as set out in the **Federal Register** of September 19, 2000 (65 FR 56468). This guidance represents the agency's current thinking on the channels of trade provision and how this provision relates to FDA-regulated products with methyl parathion residues. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the final guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The final guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.cfsan.fda.gov.

Dated: December 19, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–368 Filed 1–4–01; 8:45 am]

BILLING CODE 4160–01–F

Federal Register

Friday,
January 5, 2001

Part V

The President

Notice of January 4, 2001—Continuation of Libya Emergency

Federal Register
Vol. 66, No. 4
Friday, January 5, 2001

Presidential Documents

Title 3—

The President

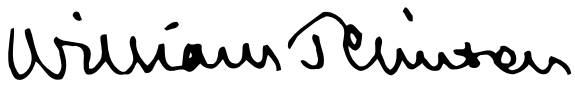
Notice of January 4, 2001

Continuation of Libya Emergency

On January 7, 1986, by Executive Order 12543, President Reagan declared a national emergency to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions and policies of the Government of Libya. On January 8, 1986, by Executive Order 12544, the President took additional measures to block Libyan assets in the United States. The President has transmitted a notice continuing this emergency to the Congress and the **Federal Register** every year since 1986.

The crisis between the United States and Libya that led to the declaration of a national emergency on January 7, 1986, has not been resolved. Despite the United Nations Security Council's suspension of U.N. sanctions against Libya upon the Libyan government's hand over of the Pan Am 103 bombing suspects, there are still concerns about the Libyan government's support for terrorist activities and its noncompliance with United Nations Security Council Resolutions 731 (1992), 748 (1992), and 883 (1993).

Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing the national emergency with respect to Libya. This notice shall be published in the **Federal Register** and transmitted to the Congress.



THE WHITE HOUSE,
January 4, 2001.

[FR Doc. 01–527
Filed 01–04–01; 11:56 am]
Billing code 3195–01–P

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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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This completes the listing of public laws enacted during the second session of the 106th Congress. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. This list is also available online at http://www.nara.gov/fedreg.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at http://www.access.gpo.gov/nara/index.html. Some laws may not yet be available.

The list will resume when bills are enacted into public law during the next session of Congress. A cumulative list of Public Laws will be published in the **Federal Register** on Tuesday, January 16, 2001.

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H.R. 4020/P.L. 106–574
To authorize the addition of land to Sequoia National Park, and for other purposes. (Dec. 28, 2000; 114 Stat. 3062)

H.R. 4656/P.L. 106–575
To authorize the Forest Service to convey certain lands in the Lake Tahoe Basin to the Washoe County School District for use as an elementary school site. (Dec. 28, 2000; 114 Stat. 3063)

S. 1761/P.L. 106–576
Lower Rio Grande Valley Water Resources Conservation and Improvement Act of 2000 (Dec. 28, 2000; 114 Stat. 3065)

S. 2749/P.L. 106–577
To establish the California Trail Interpretive Center in Elko, Nevada, to facilitate the interpretation of the history of development and use of trails in the settling of the western portion of the United States, and for other purposes. (Dec. 28, 2000; 114 Stat. 3068)

S. 2924/P.L. 106–578
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S. 3181/P.L. 106–579
National Moment of Remembrance Act (Dec. 28, 2000; 114 Stat. 3078)

H.R. 1795/P.L. 106–580
National Institute of Biomedical Imaging and Bioengineering Establishment Act (Dec. 29, 2000; 114 Stat. 3088)

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